Inspiration® Series Ventilator Technical Manual

eVent Medical

Inspiration® Series Ventilator Technical Manual

Model Numbers:

INSPIRATION®	P/N F7200000-XX
INSPIRATION® LS	P/N F7300000-XX
INSPIRATION® *infant*	P/N F7400000-XX
INSPIRATION® *infant* LS	P/N F7500000-XX

XX in the Ventilator Model Numbers indicate language configuration

Effective Firmware Versions:

Ventilator Software Version 4.3.0 through 4.7.1

Power Software Version 3.2.5

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Section

1

PREFACE

1.1 Introduction

This manual is intended to provide the necessary information required to service and maintain the eVent Medical Inspiration® series ventilator system. It is intended for use by certified biomedical engineers or engineers with equivalent experience in the maintenance of respiratory life support equipment. It is highly recommended that engineers wishing to undertake the maintenance of the Inspiration ventilator system attend a technical training seminar with eVent Medical or authorized local agents.

1.2 Copyright Information

The information contained within this manual is the sole property of eVent Medical and may not be duplicated or reproduced without written permission from eVent Medical. This manual may be revised or replaced by eVent Medical at any time without notification. Always ensure that the most current applicable version of this manual is being used, by contacting eVent Medical. While the information set forth herein is believed to be accurate, it is not a substitute for the exercise of professional judgment.

The Inspiration® ventilator system should be operated and serviced only by trained professionals. eVent Medical's sole responsibility, with respect to the ventilator, and its use, is as stated in the warranty provided.

Nothing in this manual shall limit or restrict in any way eVent Medicals right to revise or otherwise change or modify, without notice, the equipment (including its software) described herein. In the absence of an express, written agreement to the contrary, eVent Medical has no obligation to furnish any such revisions, changes, or modifications to the owner or user of the equipment (including its software) described herein.

1.3 Definitions

Throughout this manual three types of indicators are to be used to convey information in regards to the dangers associated with the proper use of the Inspiration series ventilator and to emphasize important technical requirements.

WARNING:
Means there is a possibility of injury to yourself or other persons
CAUTION:
Means there is a possibility of damage to the equipment or other property
NOTE:
Indicates a point of particular interest or special emphasis for more efficient and convenient operation of the equipment

1.4 Product Warranty

The Inspiration series ventilator system is warranted against defects in material and workmanship in accordance with the eVent medical equipment warranty for a period of 12 (Twelve) Months from the time of sale. To ensure the validity of warranty detailed maintenance records should be maintained for each device.

1.5 Year of Manufacture

The Inspiration series ventilator systems year of manufacture may be determined from the device serial number as displayed on the type label on the devices rear panel. The serial number is displayed in the following format for Inspiration, LS, and *infant* devices:

Inspiration Series Ventilator XXXX**W**YY ZZZZ

In this format the digits XXXX report the year of manufacture, W reports the place of manufacture, YY reports the model type with 02 denoting Inspiration, 03 denoting Inspiration LS, 04 denoting Inspiration *infant*, and 05 denoting the Inspiration *infant* LS. Digits ZZZZ are a sequential but individual number.

1.6 Manufacturer:

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1.7 Standards and Approvals

CE 0120	The *INSPIRATION*® Ventilator System complies with the requirements of directive 93/42/ EEC concerning Medical Devices and therefore bears the CE mark.
IEC 60601-1	Classified as protection class I, Type A, internally powered, drip-proof equipment, continuous operation.
International Standards	Meets IEC60601-1, EN794-1, ASTM1100-90, ASTM1054-87, ISO5356-1
CE Notified Body	SGS UK.

It should be noted that even at this level of device immunity certain transmitting devices (cellular telephones, cordless telephones, paging transmitters etc.) emit radio frequencies that could interrupt ventilator operation if located too close to the device.

Do not operate the ventilator in a magnetic resonance imaging (MRI) environment. The Diagnostic Error Codes and Alarm Messages section of this manual describes the possible ventilator alarms and what to do if they occur. Consult with your institution's biomedical engineering department in the case of interrupted ventilator operation, and before relocating any life support equipment.

Changes or modifications to this system not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the equipment or system and could cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulations regarding EMC and shall be installed and put into service according to the EMC information stated as follows.

WARNING:

Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

WARNING:

The equipment or system shall not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system shall be tested to verify normal operation in the configuration in which it is being used.

Compliant Cables and Accessories

The table below lists cables, transducers, and other applicable accessories for which the manufacturer claims EMC compliance.

NOTE:

Any supplied accessories that do not affect EMC compliance are not listed.

Part No.	Type	Description	Length max.
F910085	Serial	SW Download Cable	3m
n/a; Generic	Ethernet	Shielded Ethernet Cable (STP)	3m

WARNING:

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

Guidance and manufacturer's declaration – electromagnetic emissions		
The *INSPIRATION*® Ventilator System is intended for use in the electromagnetic environment specified below. The customer or the user of the *INSPIRATION*® Ventilator System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The *INSPIRATION*® Ventilator System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The *INSPIRATION*® Ventilator System is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The *INSPIRATION*® Ventilator System is intended for use in the electromagnetic environment specified below. The customer or the user of the *INSPIRATION*® Ventilator System should assure that it is used in such an environment.			
Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line (differential mode) ± 2 kV line to earth (common mode)	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	Mains power quality should bet hat of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The *INSPIRATION*® Ventilator System is intended for use in the electromagnetic environment specified below. The customer or the user of the *INSPIRATION*® Ventilator System should assure that it is used in such an electromagnetic environment.			
Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the *INSPIRATION*® Ventilator System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms	$d = 1.2\sqrt{P}$
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz inside ISM bands[a]	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the *INSPIRATION*® Ventilator System is used exceeds the applicable RF compliance level above, the *INSPIRATION*® Ventilator System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *INSPIRATION*® Ventilator System.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT

The *INSPIRATION*® Ventilator System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *INSPIRATION*® Ventilator System can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *INSPIRATION*® Ventilator System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (P) [W]	**Separation distance according to frequency of transmitter** [m]			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	**150 kHz to 80 MHz** inside ISM bands $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitter in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/transportable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1.8 Customer Assistance

Should assistance be required please contact your local eVent Medical representative or contact eVent Medical directly at service@event-medical.com.

Section

2

GENERAL INFORMATION

2.1 Introduction

This section of the manual is intended to provide introductory information concerning the Inspiration series ventilator system; along with a brief product description, specifications, a tooling and maintenance summary and an introduction to the ventilator's controls and indicators.

2.2 How to Use the Manual

The information within is not intended as a sole source of reference and has been intended for use in conjunction with the Inspiration User Manual (F910039-XX). Both manuals should be referenced when performing any maintenance to the system.

2.3 Safety Information

Only medical air or medical Heliox 80/20% (20% oxygen) and medically pure gaseous oxygen should be used with this device. All gases used must be dry and completely oil-free. Anesthetics and potentially explosive gases should not be used. Also all gas pipes, high pressure hoses, connectors and other pneumatic apparatus used must be completely oil free.

To avoid any potential fire hazard, keep all matches, lighted cigarettes, hydrocarbons, and other sources of ignition away from this device.

An alternative source of ventilation should always be available when using the Inspiration ventilator.

Do not replace any accessories or other parts of the Inspiration ventilator while a patient is being ventilated.

Maintenance work must always be carried out in compliance with all relevant safety regulations. Repairs, assembly and usage should only be carried out by trained, authorized personnel. To ensure that the device continues to perform to specification, all manufacturer's prescribed preventive maintenance guidelines should be followed.

Always use a bacteria filter between the "To-Patient" port on the Inspiration and the ventilator breathing circuit to prevent any contamination of the device.

Do not sterilize the Inspiration ventilator.

Before each use, check the water traps and filters on each of the high pressure gas inlets for any residual moisture or particles. Empty the water traps and dry them as necessary. Replace the filter elements if necessary.

If you notice the Inspiration is damaged in any way that its life supporting function can no longer be guaranteed, stop ventilation with the defective device immediately and use an alternate form of ventilation.

To avoid electrical shock while servicing the ventilator, be sure to disconnect the device from any power sources prior to commencing.

US federal law restricts this device to sale by or on the order of a physician in the U.S.A.

Do not use the Inspiration ventilator unless an internal battery with at least a minimal charge is installed. If the Inspiration ventilator has been stored for an extended period of time it is recommended that the internal battery be recharged and tested prior to use. To optimize internal battery life it is recommended to keep the ventilator plugged in to A.C. mains even when not in use.

When the Inspiration ventilator is connected to another device via the serial port or Ethernet port, the power cord should be in place to ensure adequate grounding.

2.4 Product Description and Intender Use

The Inspiration ventilator system is intended for use with a wide range of infant, pediatric, and adult patients requiring ventilatory support. The ventilator system is available with an optional internal back-up compressor and an internal rechargeable battery; therefore it may not be dependent on an external power or air supply for backup operation. When equipped as such it can be used to provide ventilation during patient transport within the hospital.

The Inspiration ventilator system is well equipped with ventilation, monitoring and safety features. Listed below are some of the key features:

- User-selected oxygen concentration.
- Volume or pressure based breaths delivered in controlled, synchronized intermittent mandatory or spontaneous modes.
- Flow or pressure triggering.
- Apnea monitoring and ventilation backup system.
- Numeric or waveform display of user-defined ventilator data.
- Respiratory mechanics monitoring.
- *Smart Sigh*™ breaths delivered at user-defined frequency and breath amplitude.
- User-defined *Smart Nebulizer*™ functions.
- *EZ-Flow* sensor allows proximal flow monitoring.
- Prioritized alarm system.
- *Spontaneous Positive Airway Pressure (SPAP)* and *Volume Targeted Ventilation (VTV)* modes.
- *MiniWeb Interface*™ option allows real-time access to the ventilator for centralized data management and trending.

Section

3

PRODUCT SPECIFICATIONS

3.1 Power and Gas Supply

AC input	100 to 240 VAC, 50/60 Hz.
Power consumption	120 VA (W).
DC input	24 VDC ± 10%.
Internal battery operating time (with fully charged battery)	≥ 120 minutes without compressor. ≤ 120 minutes with compressor operating. At 8.0 l/min minute volume, peak flow of 45 l/min, PEEP of 5 cmH_20, average peak pressure of 32 cmH_20, mean pressure of 7 cmH_20.
O_2 and air supply pressure range	29 - 86 psi (2 to 6 bar.)
Internal compressor (if installed)	15 l/min minute volume at 14.7 psi (1 bar) ambient pressure. Compressor operation is enabled or disabled in configuration screen.
Earth leakage current	< 300 µA.
Enclosure leakage current	< 50 µA.

3.2 Settings

Ventilation modes	Volume controlled synchronized mandatory ventilation (V-CMV).
	Volume based synchronized intermittent mandatory ventilation (V-SIMV).
	Pressure regulated volume control mandatory ventilation (PRVC-CMV), a volume targeted ventilation (VTV) mode.
	Pressure regulated volume control synchronized intermittent mandatory ventilation (PRVC-SIMV), a volume targeted ventilation (VTV) mode.
	Pressure based synchronized mandatory ventilation (P-CMV).
	Pressure controlled synchronized intermittent mandatory ventilation (P-SIMV).
	Spontaneous ventilation SPONT (CPAP + PS).
	Volume support (VS), a volume targeted ventilation (VTV) mode.
	Spontaneous Positive Airway Pressure (SPAP)
	Nasal Continuous Positive Airway Pressure (NCPAP)
	Nasal Continuous Positive Airway Pressure Plus (NCPAP+) (NCPAP with rate and base flow control)
	Auto Mode
Apnea backup	Selectable apnea backup modes: V-CMV; V-SIMV; P-CMV; P-SIMV, PRVC-CMV, PRVC-SIMV, SPAP
Patient type	Adult, Pediatric, or Neonate/Infant

Special functions	Smart Nebulizer, Smart Sigh, Humidity Type, SPAP Settings, Settings Lock / Unlock, Screen Brightness (contrast)100% O2, Man Insp (manual breath delivery) Inspiratory and expiratory Hold functions
Rate	Neonate/Infant: 1 to 150 b/min; Pediatric: 1 to 120 b/min; Adult: 1 to 60 b/min. Accuracy: ± 1 b/min (0 to 100 b/min), 2% (101 to 150 b/min)
Tidal volume	Infant: 5 to 100 ml; Pediatric: 40 to 500 ml; Adult: 300 to 2000 ml. Accuracy: 5 to 40 ml: ± (2 ml + 5%); 41 to 2000 ml: ± (10 ml + 5%) Heliox: ±(10 ml +10%) *Early models with model 6022 I-valve have 10 ml lower limit
Flow pattern	Decelerating, Decelerating 50%, or Square
PEEP/CPAP	0 to 50 cmH_20. Accuracy: ± (2 cmH_20 + 4%)
Pcontrol, Psupport	0 to 80 cmH_20. Accuracy: ± (2 cmH_20 + 4%)
I : E	1:9 to 4:1. Accuracy: ± (0.1 + 2%) Ti, Tp and Te Accuracy: < 10.0 seconds ±0.01 s ≥ 10.0 seconds ±0.1 s
I time	0.1 to 10 seconds.
Plateau (inspiratory pause)	0 to 42 sec.; 0 to 70 % of breath Accuracy: ± (0.05 seconds + 1%)
Oxygen	21 to 100 % FIO_2. Accuracy: ± (3 %) full scale, On internal compressor ± (6%) full scale
Trigger	Pressure: 0.5 to 20 cmH_20 Flow: Infant: 0.1-10 l/min, Pediatric: 0.1-15 l/min, Adult: 0.2 -25 l/min
	Non-invasive Ventilation (NIV) for adult and Pediatric patient types (pressure or flow triggering)
Exhalation sensitivity (Exh sens %)	10 to 80 % of inspiratory peak flow
Peak flow (spontaneous)	Infant 1- 60 l/min; Pediatric 1 - 90 l/min; Adult 1 - 180 l/min Accuracy: 1 - 10 l/min: ± (1 l/min + 10%) 11 to 180 l/min: ± (5 l/min + 10%)
Peak flow (mandatory)	Infant 1 - 60 l/min; Pediatric 1 - 90 l/min; Adult 1 - 120 l/min Accuracy: 1 to 10 l/min: ± (1 l/min + 10%) 11 to 180 l/min: ± (5 l/min + 10%)
Apnea time	3 to 60 seconds
Auto mode	Off or On
SPAP Mode Settings	Phigh + Psup High will not exceed 80 cmH_2O Plow + Psup Low will not exceed 80 cmH_2O
	5 or (Plow setting) to 50 cmH_20
Plow	0 cmH_20 to Phigh setting
Psup High	0 to (80 – Phigh setting) cmH_20
Psup Low	0 to (80 – Plow setting) cmH_20
Thigh	0.1 to (60 - Tlow setting) s
Tlow	0.2 to 59.9 s (max 60 – Thigh setting)
Cycles/min	Neonate/Infant 1-150 c/min; Pediatric 1-120 c/min; Adult 1-60 c/min; H:L (see time values) 1:59 to 59:1
VTV settings (PRVC-CMV, PRVC-SIMV, and VS modes)	
	Infant: 5 to 100 ml; Pediatric: 40 to 500 ml; Adult: 300 to 2000 ml. *Early models with model 6022 I-valve have 10 ml lower limit

3.3 Monitoring (Patient Values)

Pressure values	Ppeak (peak pressure during a breath): 0 to 120 cmH_20. Accuracy: ± (2 cmH_20+ 4%).
	PEEP (pressure at end exhalation): 0 to 120 cmH_20. Accuracy: ± (2 cmH_20+ 4%).
	Pmean (averaged mean pressure): 0 to 120 cmH_20. Accuracy: ± (2 cmH_20+ 4%).
	Pplateau (pressure at end of pause): 0 to 120 cmH_20. Accuracy: ± (2 cmH_20+ 4%).
Volume	Vte (exhaled tidal volume): 0 to 5000 ml. Accuracy: 0 to 40 ml: ± (2 ml + 5%); 41 to 5000 ml: ± (10 ml + 5%).
	Ve (exhaled minute volume): 0 to 50.0 l/min. Accuracy: ± (0.01 l/min + 5%).
	Ve Spont (exhaled spontaneous minute volume): 0 to 50.0 l/min Accuracy: ± (0.01 l/min + 5%)
	Vti (inspired tidal volume): 0 to 5000 ml Accuracy: 0 to 40 ml: ± (2 ml + 5%); 41 to 2000 ml: ± (10 ml + 5%)
Time parameters	Resp rate (measured mandatory and spontaneous breaths per minute): 0 to 300 b/min. Accuracy. 0-100 bpm ± (1 b/min +1bpm), > 100 bpm ± 2%
	Spont resp rate (measured spontaneous breaths per minute): 0 to 300 b/min. Accuracy: 0 – 100 b/min ± (1 b/min +1%), > 100 b/min ± 2%
	Ti (inspiration time) 0.1 – 10 sec. Accuracy: ± (0.01 s)
	Ti /Ttot (calculated Inspiration time divided by total cycle time)
	H:L (ratio of time at high and low PEEP levels when *SPAP* mode is active)
Respiratory mechanics	Rinsp (inspiratory resistance of airways and tubes): cmH_20/l/s Rexp (expiratory resistance of airways and tubes): cmH_20/l/s (only available on non-US units)
	Cstat (static compliance, lung stiffness): ml/ cmH_20
Special values	Oxygen (inspiratory oxygen concentration): 15 to 103 %. Accuracy: ± (6%) of full scale
	RSBI (rapid shallow breathing index, calculated respiratory rate divided by tidal volume): b/min / ml
	% Leak (Calculated leak (1-Vte/Vti) displayed as a percent)
	Spont %1hr (proportion of spontaneous breaths in the previous hour)
	Spont % 8hr (proportion of spontaneous breaths in the previous eight hours)
Time curves and loops	Pressure over time: measured proximally or internally in cmH_20 Flow over time: measured proximally or internally in l/min Volume over time: measured proximally or internally in ml Pressure-volume loop: measured proximally or internally in cmH_20 and ml. Pressure is displayed on the x-axis and volume on the y-axis. Flow-volume loop: measured proximally or internally in l/sec and ml. Flow is displayed on the y-axis and volume on the x-axis. Flow is displayed above (inspiratory) or below (expiratory) the baseline.

3.4 Alarm Limit Settings

Alarm	Range	Comments
Resp Rate High (maximum breath rate)	2 to 200 b/min	Automatic limits: V-CMV, P-CMV: set rate + 50% All other modes: monitored total rate + 50%
Resp Rate Low (minimum breath rate)	1 to 199 b/min	Automatic limits: V-CMV, P-CMV: Set rate - 50% All other modes: Monitored total rate - 50%
Ppeak High (maximum patient pressure)	1 to 80 cmH_20	Automatic limits: V-CMV, V-SIMV: monitored Ppeak + 10 cmH_20 P-CMV, P-SIMV: set Pcontrol + set PEEP + 10 cmH_20 SPONT, SPAP: set Psupport + set PEEP + 10 cmH_20
Ppeak Low (minimum pressure)	0 to 79 cmH_20	Automatic limit (all modes): set PEEP +1 cmH_20
Ve High (high expiratory minute volume)	0.1 to 50 l/min	Uses inspiratory minute volume (Vi) if proximal sensor is disabled. Automatic limits: V-CMV mode: (set rate x set tidal volume) + 50% All other modes: monitored ExpMinVol + 50%
Ve Low (low expiratory minute volume)	0.0 to 49.9 l/min	Uses inspiratory minute volume (Vi) if proximal sensor is disabled. Automatic limits: V-CMV mode: (set rate x set tidal volume) - 50% All other modes: monitored ExpMinVol - 50%
Pmean High (high mean pressure)	1 to 80 cmH_20	Automatic limits (all modes): monitored Pmean + 10 cmH_20
Pmean Low (low mean pressure)	0 to 79 cmH_20	Automatic limits (all modes): monitored Pmean - 10 cmH_20.
Vte High (high tidal volume)	10 to 2500 ml	Uses inspiratory tidal volume (Vti) if proximal sensor is disabled. Automatic limits: V-CMV, V-SIMV, PRVC-CMV, PRVC-SIMV, VS: Set tidal volume + 50% All other modes: monitored tidal volume + 50%
Vte Low (low tidal volume)	0 to 2490 ml	Uses inspiratory tidal volume (Vti) if proximal sensor is disabled. Automatic limits: V-CMV, V-SIMV, PRVC-CMV, PRVC-SIMV, VS: Set tidal volume - 50% All other modes: monitored tidal volume - 50%
Vti limit High (high inspired tidal volume)	Off, 0 to 2500 ml	Ventilator software automatically sets alarm limit to max Vt. Automatic limits do not change Vti Limit.
High delivered FIO_2	22 to 101%	Ventilator software automatically sets alarm limit to 7% (without compressor) or 15% (with compressor) above Oxygen % setting
Low delivered FIO_2	20 to 99%	Ventilator software automatically sets alarm limit to 7% (without compressor) or 15% (with compressor) below Oxygen % setting
Leak rate (maximum leak)	20 – 100% (1-Vte/Vti) %	
Apnea (interval)	3 to 60 sec	

3.5 Physical Data

Inspiration® Ventilator System	
Width x depth x height (ventilator)	13 x 15 x 19 in. (33 x 38 x 48 cm).
Weight of ventilator	48 lbs (22 kg).
Weight of stand	66 lbs (30 kg). (Deluxe version)
Inspiration® LS Ventilator System & LS *infant* System	
Width x depth x height (ventilator)	16 x 16 x 21 in. (40 x 40 x 53 cm).
Weight of ventilator	53 lbs (24 kg).
Weight of stand	66 lbs (30 kg). (Deluxe version)
Inspiration® *Infant* Ventilator System	
Width x depth x height (ventilator)	13 x 15 x 19 in. (33 x 38 x 48 cm).
Weight of ventilator	48 lbs (22 kg).
Weight of stand	66 lbs (30 kg). (Deluxe version)

3.6 Environmental Data

Operating temperature	10 to 40 °C at 10 to 80 % relative humidity.
Storage temperature	-10 to 60 °C at 5 to 95 % relative humidity.
Atmospheric operating pressure	10 to 15.6 psi (700 to 1060 mbar)
Operating altitude	< 9999 ft (3,048 m) above sea level
Oxygen inlet supply pressure	29 to 86 psi (2 to 6 bar)
Oxygen inlet supply flow	180 l/min (STPD, dry required)
Air inlet supply pressure	29 to 86 psi (2 to 6 bar) clean, dry, oil-free
Air inlet supply flow	180 l/min (STPD, dry required)

3.7 Technical Data

Maximum limited patient pressure	120 cmH_20 limited by a dedicated pressure relief valve
Maximum operating patient pressure	80 cmH_20 controlled by high pressure alarm setting
Measuring and display devices	Pressure measurements are made by solid-state pressure transducers positioned to monitor internal operating, inspiratory, and expiratory circuit pressures
Flow and volume measurement	Flow measurements are made by one of two differential pressure flow sensors, and are integrated with time to calculate inspiratory and expiratory volumes. Flow and volume measurement ranges are according to monitored data specifications
Oxygen measurement	A galvanic oxygen cell is positioned outside of the reservoir to measure the mixed oxygen concentrations from 15 to 103%
Display of monitored data, alarms and settings.	All data appears on a color liquid crystal display (LCD)

3.8 Compliance and Approvals

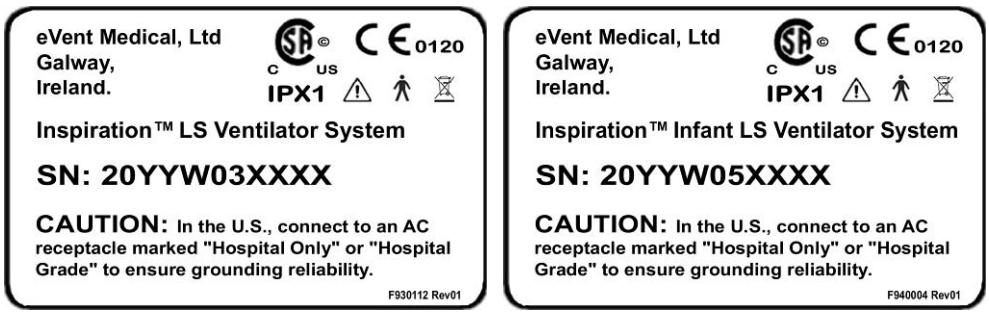
CE 0120	The INSPIRATION® Ventilator System complies with the requirements of directive 93/42/ EEC concerning Medical Devices and therefore bears the CE mark
IEC 601-1	Classified as protection class I, Type A, internally powered, drip-proof equipment, continuous operation
International Standards	Meets IEC60601-1, EN794-1, ASTM1100-90, ASTM1054-87, and ISO5356-1
CE Notified Body	SGS UK

3.9 Device Labels and Symbols

These device labels and symbols appear on the *INSPIRATION*™:

	On/Off switch
	Alarm Mute key
xxx %	Backup battery time status
BATT	On battery backup
Nebulizer	*Nebulizer* nipple connector
Flow sensor	*Flow sensor* connector
	Device connected to mains (if the green LED is on)
RS232	RS232 connection port
	Nurse call connection port
Ethernet	*Ethernet* connection port
	Refer to manual for Information or directions/warnings intended to prevent potential damage to the patient, caregiver or device
	Designates type B equipment per IEC 60601-1
IPX1	Indicates the degree of protection (drip-proof) by the enclosure
O_2 2-6bar (29-86psi)	Oxygen inlet port label
Air 2-6bar (29-86psi)	Air inlet port label
DC –Input: **24V/90W**	DC input connector
AC –Input: **100 -240VAC** **50/60 Hz** **120VA** **100V: 1.4A** **240V: 0.5A** **Fuse: 3.15AT**	AC input connector
O_2 sensor	Oxygen sensor location
SN:	Device serial number
To Patient	Gas flow to patient from ventilator
From Patient	Gas flow from patient to ventilator
Do not obstruct!	Do not obstruct port or outlet
	Internal battery compartment

The *INSPIRATION*® back panel labels:



Indicates WEEE (Waste Electrical and Electronic Equipment) Registration per EU WEEE Directive, 2002/96/EC

The internal compressor is not installed

3.10 Tools, Test Equipment and Materials (recommended)

Description	**Manufacturer / Part No**
Test Equipment:	
Pneumatic Analyzer	TSI Certifier Plus or equivalent
Electrical Safety Tester	Biotek 601 Pro or equivalent
Desktop / Laptop PC	Local Supply
Software Download Cable	eVent Medical, F910085
Adult Tubing System	Local supply
Pediatric Tubing System	Local Supply
Infant Tubing System	Local Supply
Proximal Flow Sensor, Adult	eVent Medical, F910203
Proximal Flow Sensor, Infant	eVent Medical, F910204
Exhalation Cover	eVent Medical, F710214
Exhalation Membrane	eVent Medical, F710213
Test Lung, Kit	eVent Medical, F910215
Infant test lung	eVent Medical, F910355
High Pressure Air Supply with Adjustable Pressure Regulator	Local Supply (medical grade)
High Pressure Oxygen Source	Local Supply (medical grade)
External Battery	eVent Medical, F710520
External Battery Charger	eVent Medical, F710521
Isopropyl Alcohol Cleaner	Local Supply

Description	Manufacturer / Part No
Hand Tools:	
Hex Drivers, following sizes: 1.5mm, 2mm, 2.5mm, 3mm, 4mm, 5mm	Local Supply
Torx Drivers: T8, T20	Local Supply
Open End Wrench, following sizes: 8mm, 10mm, 14mm, 16mm, 17mm, 18mm, 19mm, 20mm	Local Supply
Flat Bladed Screwdriver	Local Supply
Philips Screwdriver No 1, 2,	Local Supply
Static Dissipative Service Kit	Local Supply
Cable Ties, small	Local Supply

3.11 Recommended Preventive Maintenance

Service Interval	Action Required	Part Number
250 hours, or 1 year of use, or as required	Clean or replace fan inlet filter	F910214 Fan Filter Element (5 pack)
Every year of use	Full Performance Verification Test, in accordance with the Performance Verification section of this manual	
Every 12 months of use or as required	Replacement of high pressure inlet filters	F910300 Inlet gas filters (includes two high pressure inlet gas filters) or F930136 Non-Consumable PM kit (Includes F910300 and F910214)
	Replacement of the internal oxygen sensor	F910028 O2 sensor
Every 24 months of use or as required	Replacement of internal battery pack	F910251 (includes two batteries)
As required	Replace External Battery (optional, if installed)	F710520
	Inspect compressor inlet filter,	F810044

Section

4

THEORY OF OPERATION

4.1 Introduction

This section has been provided to detail the operational theory of the Inspiration ventilator system. It includes an overview of the ventilator operation and discusses in detail the operational principals of both the pneumatic and electronic systems. This section also describes the operation of the ventilator's firmware in interfacing and controlling the two systems.

4.2 Overview of Inspiration Operation

The Inspiration Ventilator System ® consists of two major systems, the pneumatic system and the electronic system. These systems combine under software control to deliver respiratory support at operator determined parameters. The pneumatics, under the control of the microprocessor, supplies air and oxygen to the patient system external to the device. The electronic system inputs and supervises the electrical power sources to the unit and provides electronic sensing and control of the ventilator's components.

High pressure air and oxygen enter the unit from an external source via the high pressure gas connectors. The gas is conditioned to remove moisture and particulate matter. Two solenoids control the amount of air and oxygen supplied to the mixed gas reservoir. Gas supplied to the patient exits the reservoir through a proportional valve, which is servo controlled using feedback from internal flow and pressure sensors. An active expiratory valve is used to regulate pressure levels in the patient tubing system during inspiration and exhalation.

Pressure sensors, flow sensors, and other sensors are used throughout the system to provide feedback measurements to the microprocessor. After undergoing digital conversion these measurements are used in the control of breath delivery, patient, and system monitoring.

Ventilation parameters are programmed by the operator using an Encoder switch in conjunction with the touch sensitive user interface display and dedicated keys on the ventilator front panel. Touch sensitive user interface displays may not be available on all units. Contact eVent Medical for upgrade kit information.

Power to operate the device may come from AC mains, an external 24VDC battery, an external 24 VDC power source, or from internal batteries. In the event of a loss of AC mains the unit is powered from the external battery (if available) or from the internal batteries for a limited period of time.

4.3 Inspiration Pneumatic System

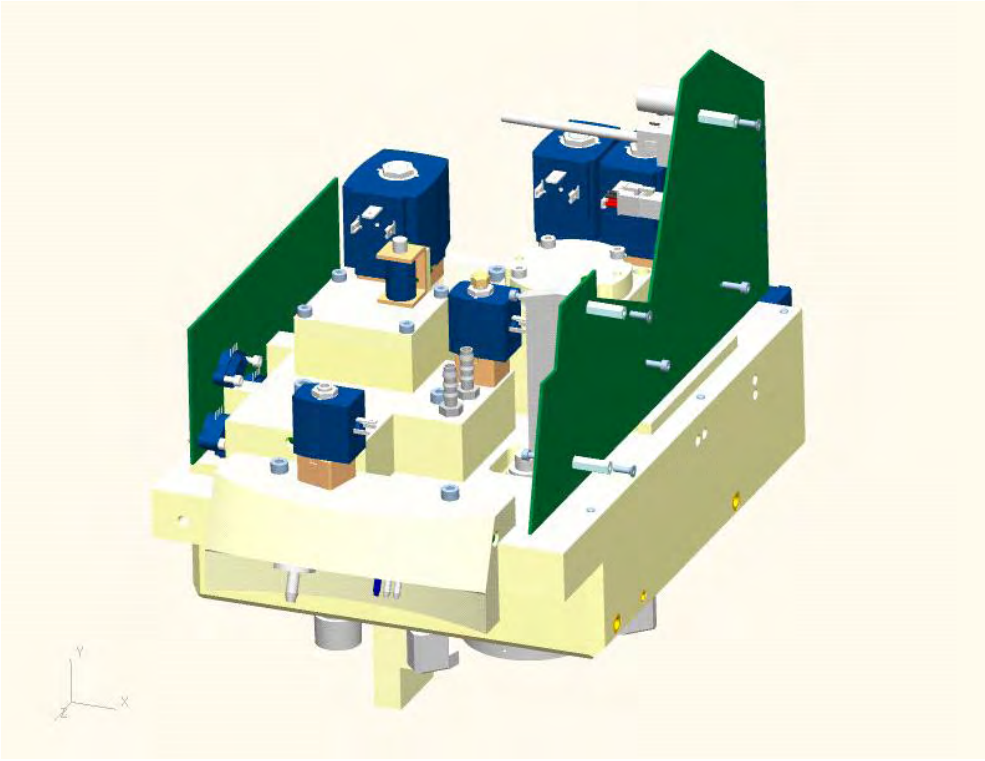


Figure 4-1

The Inspiration series ventilator pneumatic system incorporates an innovative manifold design, which virtually eliminates the need for any internal ventilator tubing. The system also incorporates an intelligent blending system eliminating the need for in-line regulators. Under microprocessor control the pneumatic system regulates and mixes the high-pressure source gasses for delivery to the patient. Internal and proximal transducers provide feedback at all times to control breath delivery and monitor patient data.

The Inspiration pneumatic system may be categorized into the following subsystems. These subsystems are described in detail within this section of the manual:

- Gas Inlet System
- Air / Oxygen Blending System
- Gas Delivery System
- Safety Valve system
- Proximal Measurement System
- Exhalation System
- Oxygen Monitoring System
- Nebulizer System

Pneumatic System Schematic Diagram

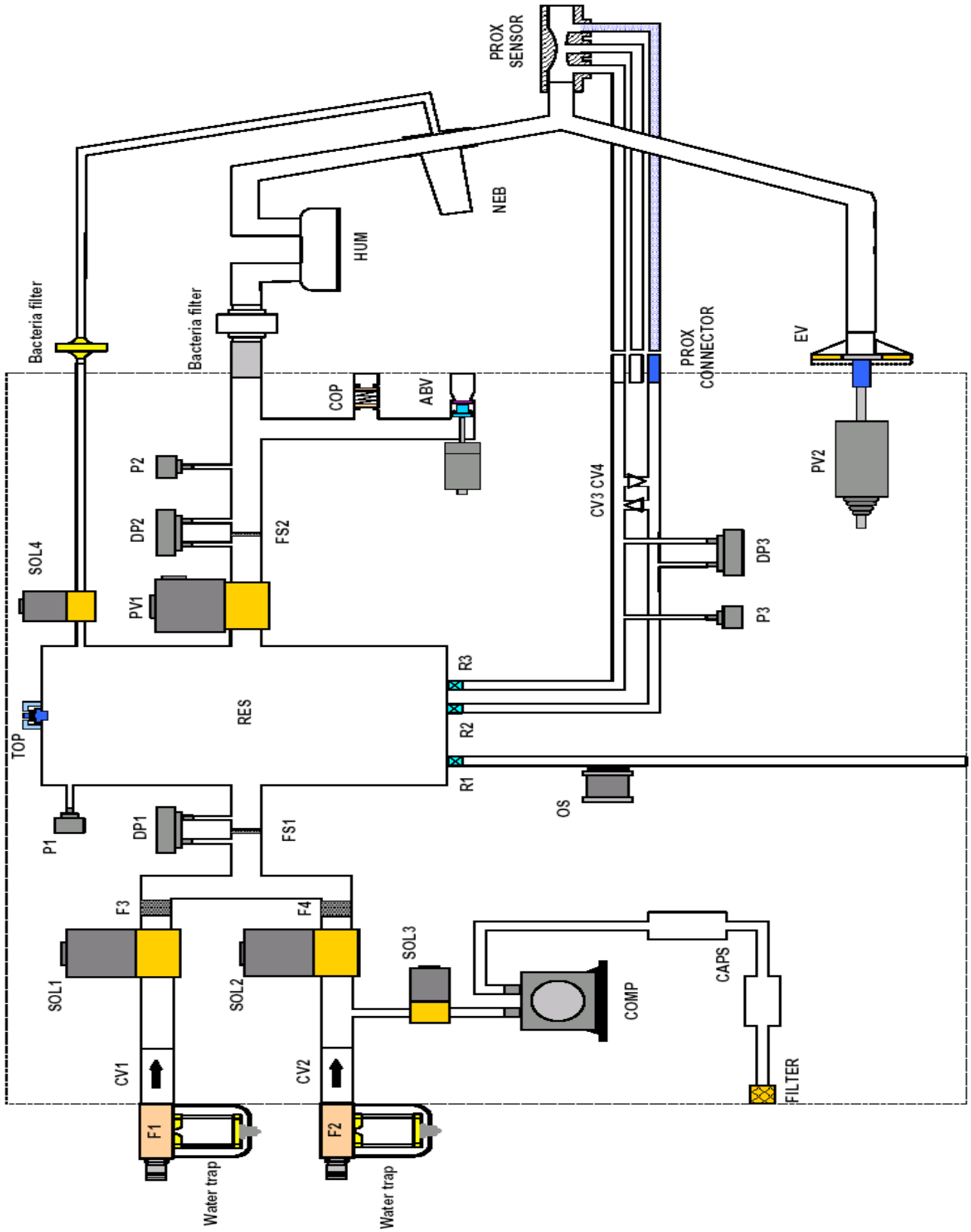


Figure 4-2

4.4 Gas Inlet System

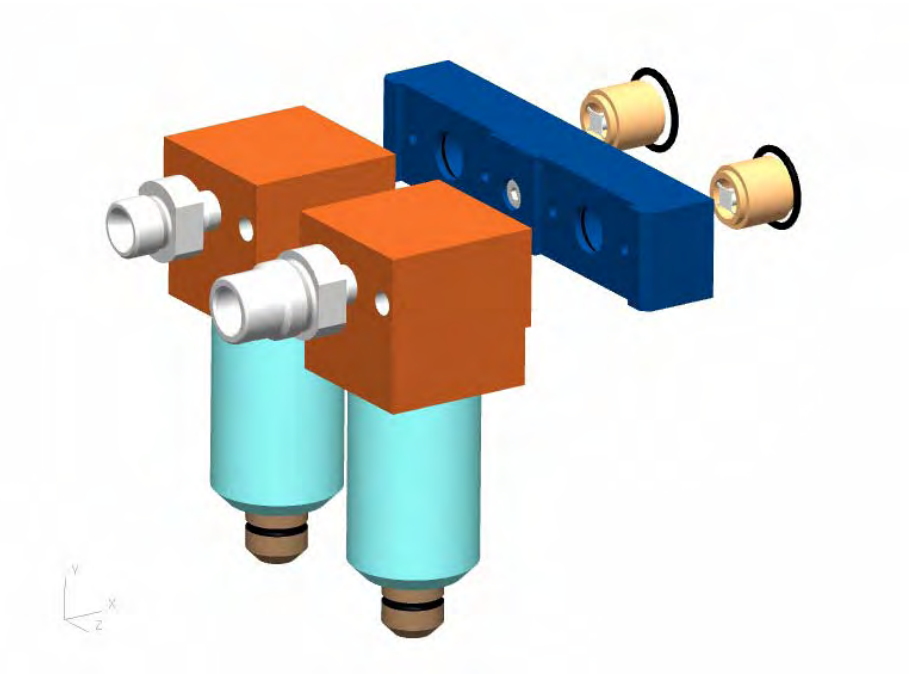
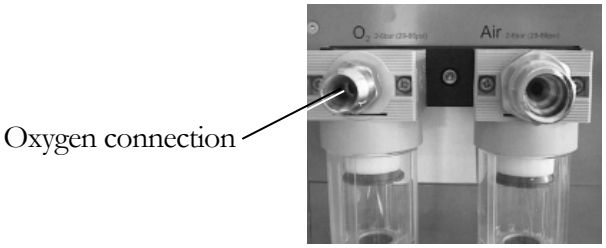


Figure 4-3

The gas inlet system (Figure 4-3) permits the connection of high-pressure air and oxygen sources to the ventilator via the high-pressure connectors. It filters the gas by removing moisture and particulate matter (≥5um), and then it directs the gasses to the blending system. The components, which comprise the gas inlet system, are described in the following paragraphs.

4.4.1 High Pressure Inlet Connectors



DISS connection nut for oxygen

Supply pressure range: 29 – 86 psi (2 to 6 bar)

DISS connection nut for air supply

Supply pressure range: 29 – 86 psi (2 to 6 bar)

Figure 4-4

The Inspiration ventilator is supplied in its standard configuration with two DISS (Diameter Indexed Safety System) high-pressure fittings for the connection of medical grade air and oxygen (Figure 4-4).

On request alternate adapters and high pressure hoses may be provided to allow connection to other international gas supply standards e.g. NIST (Non Interchangeable Screw Thread).

4.4.2 Water Traps (WT1/WT2)

The high-pressure gases are directed against the walls of the water trap bowl. This causes a momentary increase in its internal pressure, prompting any carried moisture to be released (Figure 4-5).

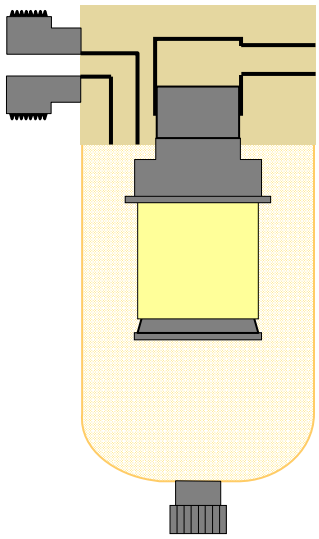


Figure 4-5

4.4.3 Inlet Filters (F1/F2)

The gas passes through inlet particulate filters. Oxygen will pass through filter F1 and Air through filter F2. The function of the particulate filter is to prevent contaminants down to a size of 5 microns from entering into the ventilators blending system. The two filters must be replaced at an annual interval or more often as conditions require.

Note:

Failure to replace the inlet filters at the prescribed maintenance interval may compromise the operation of components downstream of the system. If the device is to be operated in a location with Air or Oxygen sources which are known to be susceptible to moisture and/or contaminants, additional measures should be taken. In such instances the manufacturer strongly recommends the use of additional filter/water traps or hydrophobic filters upstream of the ventilator inlets.

4.4.4 Inlet Check Valves (CV1/CV2)

Inline check valves (Figure 4-6) prevent any back-flow of gas from the device into the high-pressure facility supplies. The check valves allow unobstructed flow of high-pressure gas into the ventilator. CV1 is located in the O_2 supply path and CV2 is located in the Air supply path.

Figure 4-6

4.5 Blending System

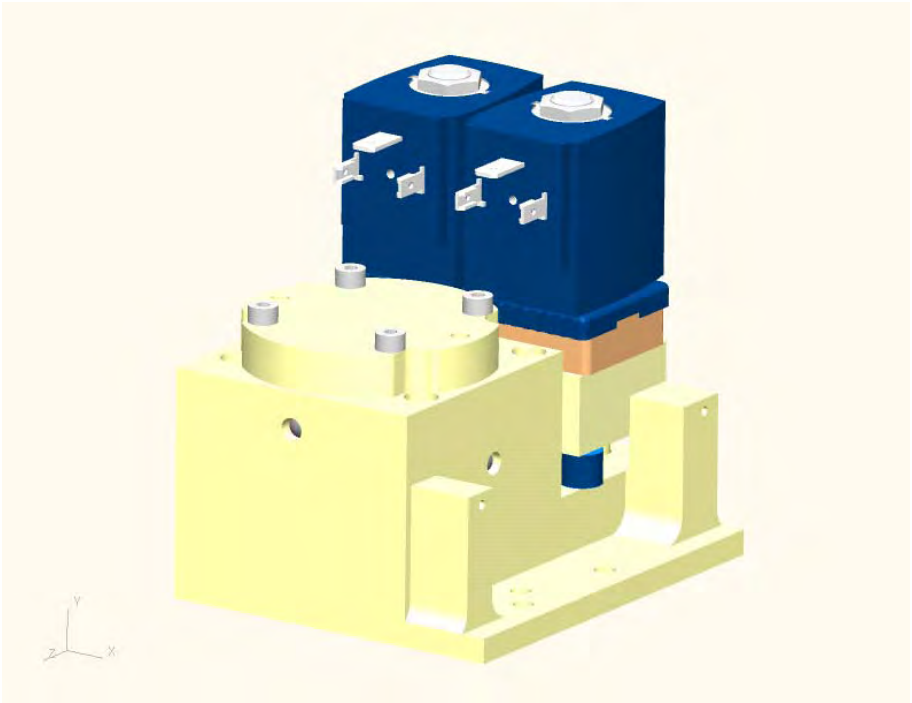


Figure 4-7

4.5.1 General Operation

Gas blending is achieved through the use of two solenoid valves and a flow measurement system. The solenoid valves are microprocessor controlled, using feedback from the blender flow measurement system, to keep the mixed gas reservoir adequately pressurized with the correct mixture of air and oxygen.

Pressure sensor P1 is used to determine when a blending cycle is required. The frequency of the blending cycles is dependent upon the amount of gas being demanded by the current ventilator

settings and other incidental requirements such as purge flow and oxygen sample flow. The device maintains the reservoir pressure within an acceptable range according to patient type. A blending cycle is initiated whenever the microprocessor determines there is insufficient gas within the reservoir to maintain the current patient requirements. The microprocessors' decisions are based on normal patient settings, base/bias flow for triggering, proximal purge flow, and oxygen requirements, all which draw upon the reservoir. At the initiation of each blending cycle the microprocessor determines what volume of gas is required from each of the high-pressure supply systems, in order to adequately recharge the reservoir with the correct air and oxygen mixture. Blender valves (Sol 1 and Sol 2) are activated sequentially during the blending cycle to supply these requirements. As the first blender valve is energized the microprocessor monitors the flow being delivered through the blender flow sensor (FS1/dP1). When it determines that the appropriate volume of gas (air or oxygen) has been delivered, the corresponding valve is de-energized. After a brief pause the second blender valve (if gas mixing is required) is energized, its flow monitored, then de-energized in the same way. The blender valves maintain an accurate air and oxygen mixture regardless of the supply conditions. If inlet gas pressure and flow decrease, the microprocessor increases the operation time for the corresponding valve until the required volume is delivered. Likewise, if the inlet pressure and flow increases the blender valves are energized for a shorter period of time to achieve the correct mix of air and oxygen.

4.5.2 Compressor Switchover

During a normal blending cycle, if the microprocessor observes a flow at FS1/dP1 of less than 30 l/min, it assumes the high-pressure air supply has been lost or compromised. If an optional internal back-up compressor is installed, the device will turn it on. When FS1/dP1 observes a flow greater than 36 l/min, indicating the high-pressure air supply has been restored, the device switches the internal compressor off.

4.5.3 Blender Solenoid Valves SV1/SV2

The Blender Solenoid Valves (Figure 4-7) are energized as needed to ensure that the correct mixture of gas is maintained within the reservoir. Solenoid 1 (SV 1) controls the flow of oxygen through the blending system. Solenoid 2 (SV 2) controls the flow of air though the blending system. The solenoid valves are mounted on a separate dampened block to reduce the sound of valve operation. Gas is directed to and from the solenoid valves by two extension tubes per valve.

4.5.4 Blender Impact Filters (F3/F4)

Located between the outlet of each blender solenoid valve and the inlet of the extension tube is a small sintered bronze impact filter (F3 - O_2 / F4 - Air.) The impact filters collect any particulate matter greater than approximately 40 microns.

4.5.5 Blender Flow Measurement (FS1/dP1)

Gas flow delivered through Sol 1 and Sol 2 during each blending cycle is measured by the blender flow measurement system (Figure 4-8). The blender flow measurement system is comprised of a sintered bronze resistive element (FS1) positioned in the path of gas flow and a corresponding differential pressure sensor (dP1), which is located on the Power board. Gas flow passing through the resistive element (FS1) causes a pressure drop across it. This pressure differential is measured by pressure transducer (dP1). The pressure differential measured at (dP1) is directly proportional to the amount of gas flow through the resistive element. This measurement is used to determine the correct gas mixture within the reservoir.

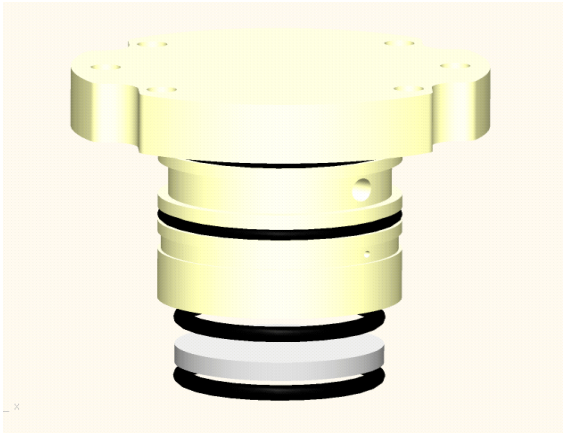


Figure 4-8

4.5.6 Internal Compressor (Comp) (optional item)

The ventilator may be equipped with an internal back-up compressor system (Figure 4-9.) In the event of a loss of facility air pressure the system will signal the internal compressor (Comp) to turn on. The internal compressor is a dual piston design and operates on DC voltage, thus allowing operation using the internal battery. The compressor draws room air into the pneumatic system through a sintered bronze inlet filter element located at the rear of the pneumatic module. Air is routed through the upper pneumatic block, sensor block 2, and into the compressor. Compressed air exits the compressor and is routed through sensor block 2 and the compressor-unloading valve (Sol 3) then into the reservoir.

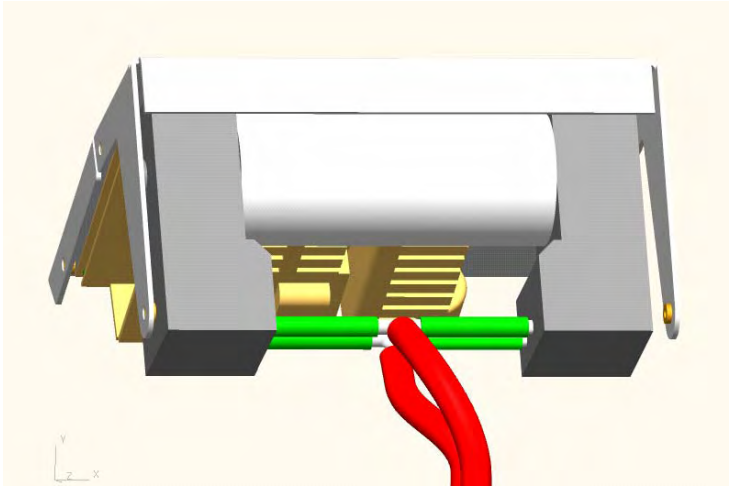


Figure 4-9

4.5.7 Compressor Unloading Valve (Sol 3)

Air from the internal compressor is routed into the reservoir via the compressor unloading solenoid valve (Sol 3). Sol 3 is a normally open three-way solenoid (Figure 4-10.) The open port is vented to atmosphere. During compressor startup Sol 3 remains de-energized allowing the compressor to start with no load. Sol 3 is then energized to route the compressor output to the reservoir. A small bronze muffler is attached to the normally open port of Sol 3 in order to silence the sound of the venting air.

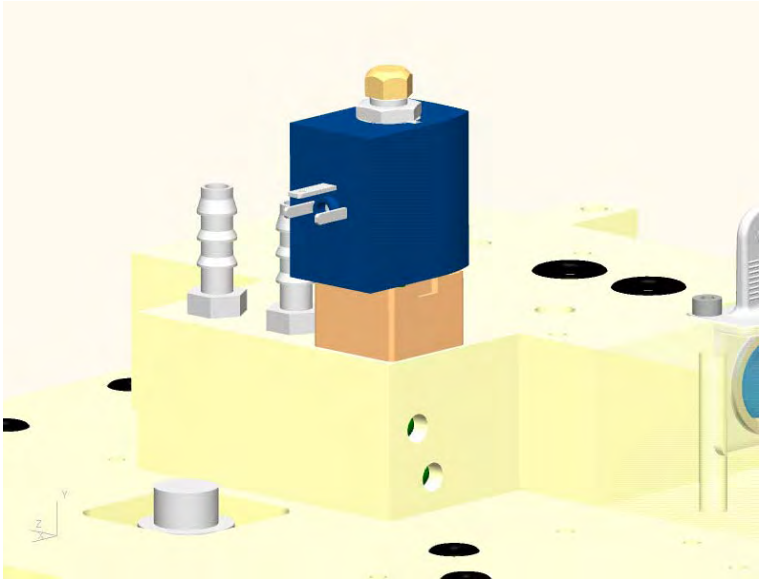


Figure 4-10

4.5.8 Reservoir Assembly (Res)

The reservoir (Res) serves as a storage chamber for mixed gas which is available for delivery to the patient and for other incidental requirements such as purge flow. The reservoir (Figure 4-11) consists of a number of separate interconnected chambers that provide approximately one liter of compressible volume. The pressure in the reservoir is maintained within a pressure range specific to the patient type selected.

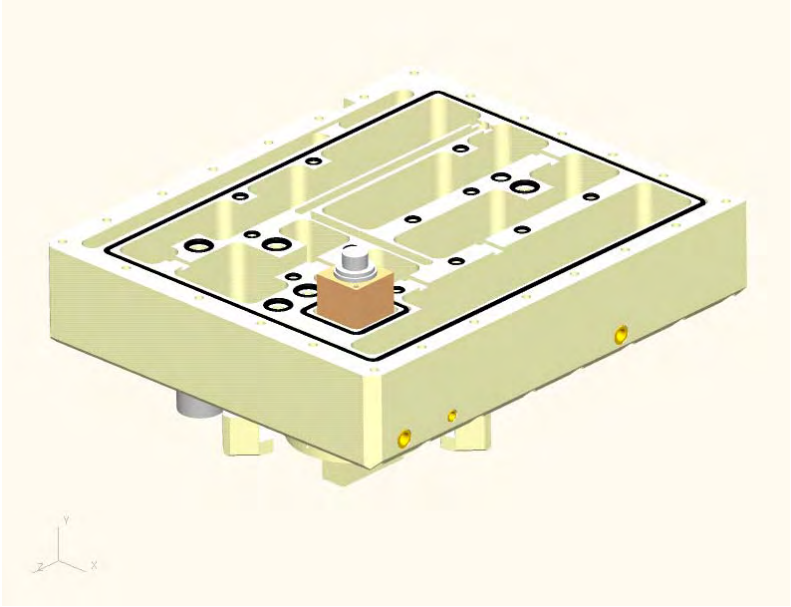


Figure 4-11

4.5.9 Reservoir Pressure Measurement (P1)

The internal pressure of the reservoir is monitored at all times by the reservoir pressure transducer P1. This measurement is used by the microprocessor to assess the reservoir's fill state and determines when blending cycles must be initiated. Pressure transducer P1 is located on the Power board mounted on the pneumatic chassis.

4.5.10 Reservoir Over-Pressure Valve (OPV)

The reservoir over-pressure valve (OPV) is incorporated into the upper block of the reservoir (Figure 4-12). This factory set mechanical relief valve will open in the event the reservoir's internal pressure exceeds 1.8 bar (26 psi.)

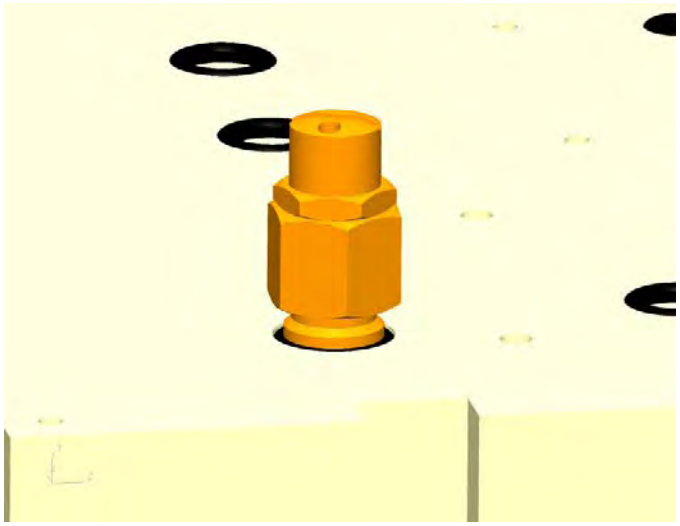
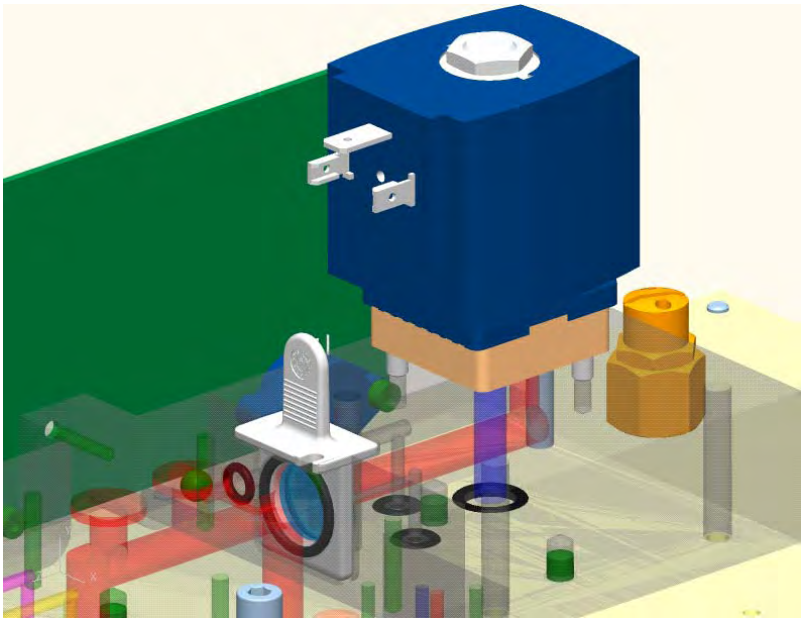


Figure 4-12

4.6 Gas Delivery System



4.7 Inspiratory Proportional Valve (PV1)

The inspiratory valve (PV1) is microprocessor controlled using feedback from the internal flow (FS2) and pressure (P2) measurement transducers situated at its output. With the exception of FiO_2 all breath delivery parameters are controlled by the inspiratory proportional valve (PV1). Gas from the delivery system is routed to the patient tubing system. As the controlling, Pulse Width Modulation (PWM) is increased, PV1 opens proportionally further, allowing more flow to pass through it. As the controlling PWM is decreased, PV1 begins to close, resulting in less flow passing through. All aspects of breath delivery are regulated by the PV1 using feedback from the internal breath delivery transducers FS2/dP2 and P2. During volume-targeted breaths, PV1 is regulated using feedback from the internal flow sensor (FS2/dP2) so as to control the tidal volume, peak inspiratory flow and breath shape. (Figure 4-13)

Figure 4-13

4.7.1 Internal Flow Measurement (FS2/dP2)

Flow delivered through the inspiratory proportional valve PV1 is monitored by the internal flow measurement system. The internal flow measurement system is comprised of a resistive mesh element (FS2), positioned at the outlet of PV1. Gas flow passing through FS2 causes a pressure drop across it. The differential pressure is measured at pressure transducer dP2, located on the Sensor board. The differential pressure measured at dP2 is directly proportional to the amount of gas flow through FS2. Feedback from the internal flow measurement system is used by the microprocessor to regulate the operation of the proportional valve for volume and flow delivery applications (Figure 4-14).

Figure 4-14

4.7.2 Internal Pressure Measurement (P2)

The internal pressure of the breath delivery circuit is monitored at all times by pressure transducer P2. This measurement is used by the microprocessor to regulate the operation of the proportional valve (PV1) and the expiratory valve (PV2) for pressure regulated breath delivery applications.

4.7.3 Safety Valve Block

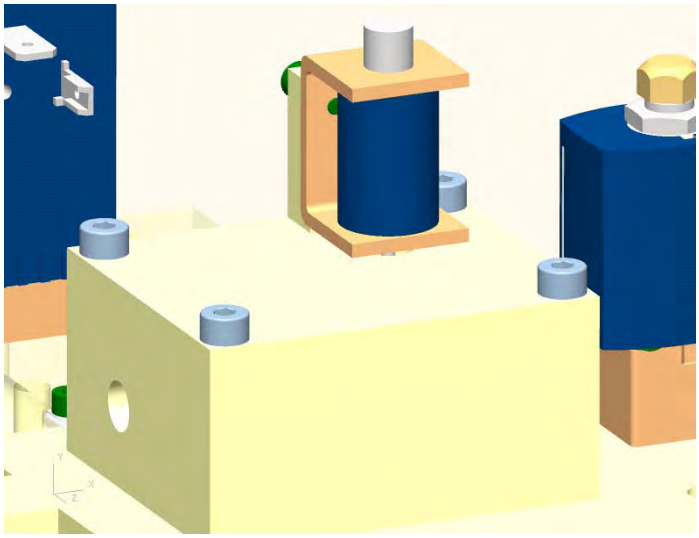


Figure 4-15

To protect the patient during abnormal operation, the ventilator has two separate safety devices that are incorporated into the safety valve block. The safety valve block interfaces with the main gas delivery path and incorporates both a mechanical high pressure relief valve and an electromechanical safety valve (Figure 4-15).

4.7.4 High Pressure Relief Valve (HPRV)

In order to protect the patient's airway from any harm that might result from a continuous high pressure event, a High Pressure Relief Valve (HPRV) is incorporated into the devices safety valve block. The HPRV is a mechanical relief valve with a set cracking pressure of 120cmH_2O. The HPRV opens automatically venting excess pressure to atmosphere when pressure in the patient system exceeds 120cmH_2O (Figure 4-16).

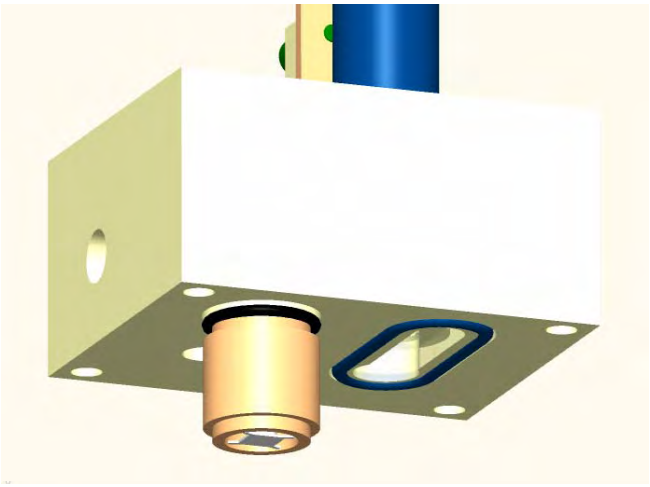


Figure 4-16

4.7.5 Safety Valve (SV)

A Safety Valve (SV) is incorporated in the safety valve block in order to provide the patient with an open breathing path from ambient air in the event of an emergency. The safety valve is comprised of a sealing disc and corresponding sealing surface which functions like a check valve. A solenoid valve is also included in the system, which under normal operating conditions is energized. In this condition the valves plunger is extended holding the sealing disc hard against its seat and closing off the ambient port. In the event of a critical error condition (e.g. Technical fault) the solenoid is de-energized retracting the plunger away from the sealing disc. Under these conditions the sealing disc will remain loosely in position on its sealing surface and allowing it to function as an inspiratory check valve. Any inspiratory effort on the part of the patient will result in the sealing disc being displaced and inspiratory flow being drawn into the system from atmosphere. As the patient begins to exhale the sealing disc is forced against its sealing surface thus closing off the ambient port. Patient exhalation under safety valve open conditions is achieved through the open expiratory system (Figure 4-17).

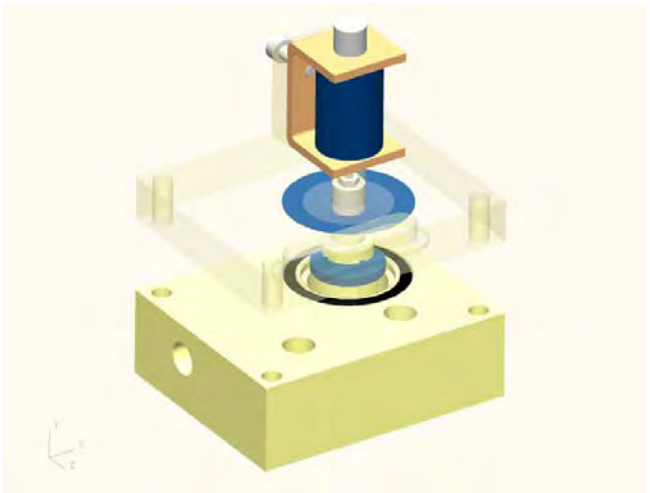


Figure 4-17

4.8 Proximal Measurement System

A flow sensor may be used proximally to provide the operator with feedback on the patient's exhaled tidal volume and proximal airway pressures. The proximal sensor also allows the flow-triggering functionality to be used. Transducers mounted internally on the Sensor board are used in all of these functions. A proximal purge flow (rinse flow) is provided at all times to keep the sensing lines free and clear of moisture, patient secretions and prevents contamination from entering the ventilator via the flow sensor lines. Over-pressure protection, provided by CV3/CV4, is incorporated to ensure that purge pressure does not damage the differential pressure transducer (dP3) in the event of an occlusion of the flow sensor tube(s). The use of the proximal flow sensor is optional. If the proximal sensor is not used the ventilator must be configured with the flow sensor turned off. If no proximal flow sensor is used the ventilator disables patient monitoring derived from proximal measurements and flow triggering.

Figure 4-18

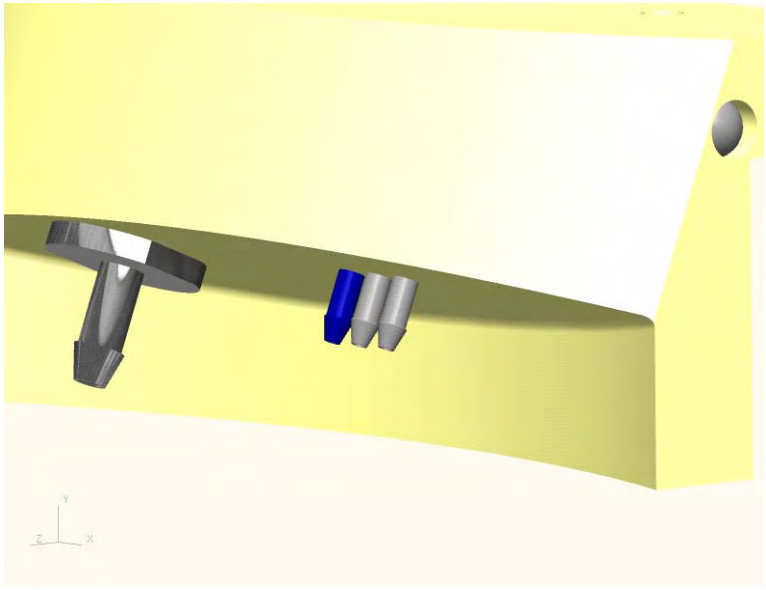
4.8.1 Proximal Flow Measurement (FS3/dP3)

The proximal flow sensor (Figure 4-18) is used to provide feedback on patient exhaled volumes and flow triggering. The flow sensor is available in 2 sizes, Adult/Pediatric and Infant/Pediatric types and may be single patient use or re-usable (sensor body only.) The proximal flow measurement system is comprised of a flow sensor (FS3), which is positioned directly in the path of the patients exhaled gas flow, and a corresponding differential pressure sensor (dP3), which is located on the Sensor board inside the ventilator. Gas flow passing through the flow sensor (FS3) will causes a pressure drop across it. The two outer tubes of the flow sensor carry the pressure signals back to the device where they measured at pressure transducer dP3. The pressure differential measured at dP3 is directly proportional to the amount of gas flow passing through the flow sensor. This is used by the microprocessor to calculate and display values for Vte, Ve and Ve Spont. Additionally, this information is used to make alarm (volume) decisions and to determine if the patient flow-trigger threshold has been reached.

4.8.2 Proximal Pressure Measurement (P3)

The proximal pressure, at the patient wye, is monitored at all times by the proximal pressure transducer (P3). The pressure transducer P3, located on the Sensor board, tees into the upstream pressure line of the proximal flow sensor. This measurement is used by the microprocessor to calculate and display values for Ppeak, Pplateau, Pmean and PEEP. Additionally this information is

used to make alarm (pressure) decisions and to determine whether the patient pressure trigger threshold has been reached.



4.9 Proximal Purge System

The use of proximal measurement systems can be prone to problems related with migration of moisture, patient secretion and/or contamination back towards the device. To combat this, the Inspiration ventilator operates at all times with a highly efficient proximal purge system. A small purge flow is developed by two restrictors/orifices (R2/R3), located within sensor block 2. This allows a small gas bleed (approx 4ml/min nominal) of flow from the reservoir, down through each of the outer proximal sensing lines. The proximal purge flow developed is sufficient to prevent moisture from entering the lines. The purge flow restrictors are matched during the manufacturing process to ensure that there is no resulting offset on dP3.

4.9.1 Proximal Over Pressure Protection

In order to prevent damage to the differential pressure transducer (dP3), which could result from an occlusion of a proximal sensing line, the system incorporates over pressure protection provided by two check valves (CV3/CV4). The check valves have a cracking pressure of 100 cmH_2O and are biased to allow flow in either direction in the event of an over pressure fault condition. If the pressure differential between the lines exceeds 100 cmH_2O the check valve opens and vents the excess pressure into the opposite proximal line equalizing the pressure on both sides of the differential pressure transducer.

4.10 Exhalation System

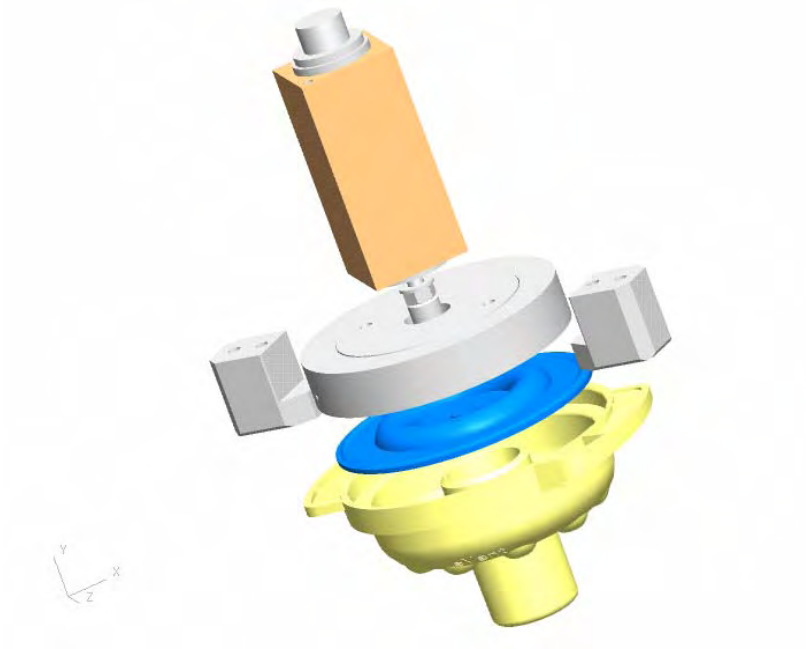


Figure 4-19

4.10.1 Exhalation System Operation

The exhalation systems function is to seal the patient system during the inspiratory phase of ventilation (Figure 4-19). During the expiratory phase of ventilation the exhalation system will open allowing patient exhalation and, where required, maintenance of the prescribed PEEP baseline.

The exhalation system is comprised of a reusable cover and membrane that acts to seal the patient system under the control of the exhalation valve (PV2). During inspiration, with volume targeted breath delivery, the exhalation valve is controlled to the fully energized setting applying the maximum closing force on the exhalation membrane and cover. The exhalation valve remains fully closed throughout all volume controlled breath deliveries. During inspiration, with pressure targeted breath delivery, control is applied to the valve to maintain the target pressure. Any excess pressure within the system is released through the exhalation valve. The exhalation valve is proportionally controlled, using feedback from the internal pressure transducer P2. During exhalation, only as much control is applied to the valve as is required to maintain the operator set level of PEEP. With the exhalation valve fully de-energized, as might result in the event of a critical error (technical fault) being detected, the exhalation membrane and cover will function as an expiratory check valve to compliment safety valve operation. During this Safety Valve Open (SVO) condition, any inspiration effort from the patient will pull the exhalation membrane closed on its seat. Any patient expiratory effort will displace the exhalation membrane from its seat allowing exhaled gases to exhaust to atmosphere.

4.10.2 Exhalation Valve (PV2)

The exhalation proportional valve (PV2) is controlled by varying the controlling Pulse Width Modulated (PWM) signal. As the controlling PWM is increased PV2 (Figure 4-20) applies an increasing amount of downward torque to its plunger. The exhalation valve plunger presses downward upon the exhalation membrane and cover to seal the patient tubing system. The operation of the exhalation valve is microprocessor regulated using feedback from the internal pressure transducer P2.

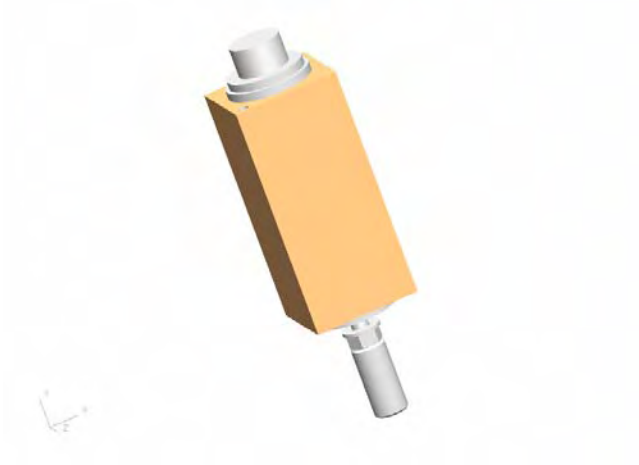


Figure 4-20

4.10.3 Exhalation Cover

The exhalation cover (Figure 4-21) provides the seating component for the exhalation membrane. It includes a single and central From Patient port for connection of expiratory tubing and has a number of exhaust ports around its circumference for minimal expiratory resistance. The exhalation cover is reusable and is certified for up to 100 sterilization cycles with maximum temperature of 134°C (275°F).

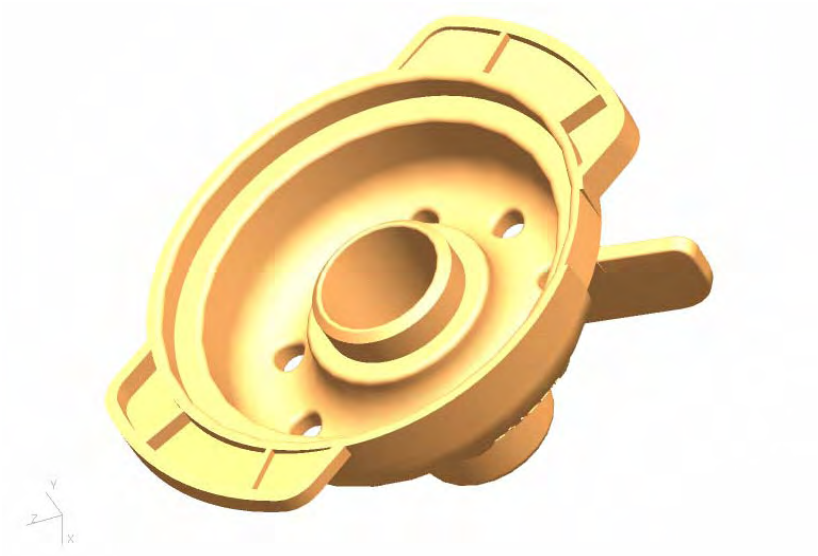


Figure 4-21

4.10.4 Exhalation Membrane

The exhalation membrane (Figure 4-22) under the force of the exhalation valve plunger is pressed against the seating surface of the exhalation cover with the required amount of torque in order to seal the patient system. The exhalation membrane is reusable and is certified for up to 10 sterilization cycles with maximum temperature of 134°C (275°F.)

Figure 4-22

4.11 Oxygen Monitoring

The oxygen monitoring system (Figure 4-23) provides the operator with a real-time indication of the oxygen percentage being delivered to the patient. The system incorporates an oxygen sensor (OS), which uses galvanic fuel cell technology, to develop an output voltage which is proportional to the partial pressure of oxygen within the sampled gas. The sample flow is developed by a restrictor/orifice (R1) whose inlet source is the reservoir. The small gas sample (0.4 l/min nominal) travels down through the oxygen sensor block and is directed through a jet onto the heart of the oxygen sensor. The sample gas is then exhausted to atmosphere. The oxygen sensor interfaces with circuitry on the Sensor board. The microprocessor uses this information to display the measured oxygen % on the monitoring screen and to evaluate whether alarms thresholds have been violated. A preset alarm is activated when the monitored oxygen % falls outside of the allowed range. The manufacturer recommends replacement of the oxygen sensor after every 12 months of operation, or as required. Failure to do so may result in an inaccurate monitored oxygen %. The oxygen sensor may be fully calibrated using the automated function available on the User calibration screen. Additionally, a single point calibration can be performed whenever the 100% O_2 function is selected and allowed to finish the five-minute time interval.

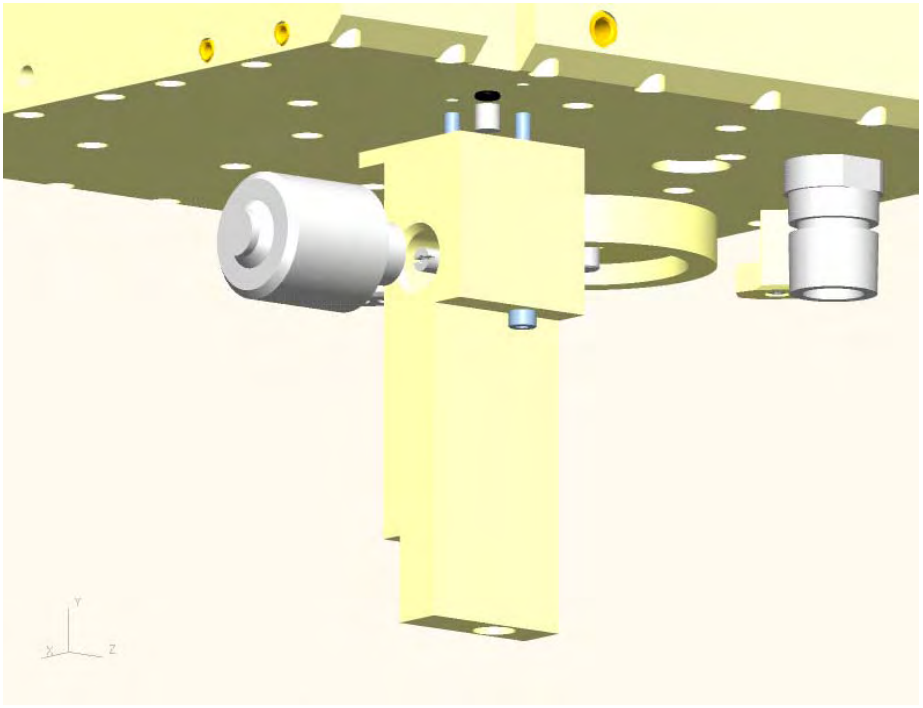


Figure 4-23

4.12 Nebulizer System

The Inspiration ventilator incorporates a pneumatic, microprocessor controlled, smart nebulizer system (Figure 4-24). At the required intervals the ventilator drives gas down through the nebulizer circuit (if connected) in order to facilitate patient nebulization.

The inlet source to the internal nebulizer is reservoir gas at the operator set oxygen level and consequently the monitored oxygen percentage is unaffected while nebulizer therapy is taking place. During inspiration, in volume or pressure targeted ventilation modes, the nebulizer solenoid is energized diverting gas through the nebulizer circuit. The microprocessor assesses the amount of gas passing to the nebulizer circuit on a breath-by-breath basis and adjusts the volume and pressure delivered through the inspiratory valve by the appropriate proportion to compensate. Operating in this way will maintain delivered tidal volumes and pressures within an acceptable level of accuracy. When inspiratory flow drops below 5 l/min the nebulizer valve is switched off. The internal nebulizer is not available in the Inspiration *Infant* Ventilators or when the infant mode is selected on the Inspiration or LS models.

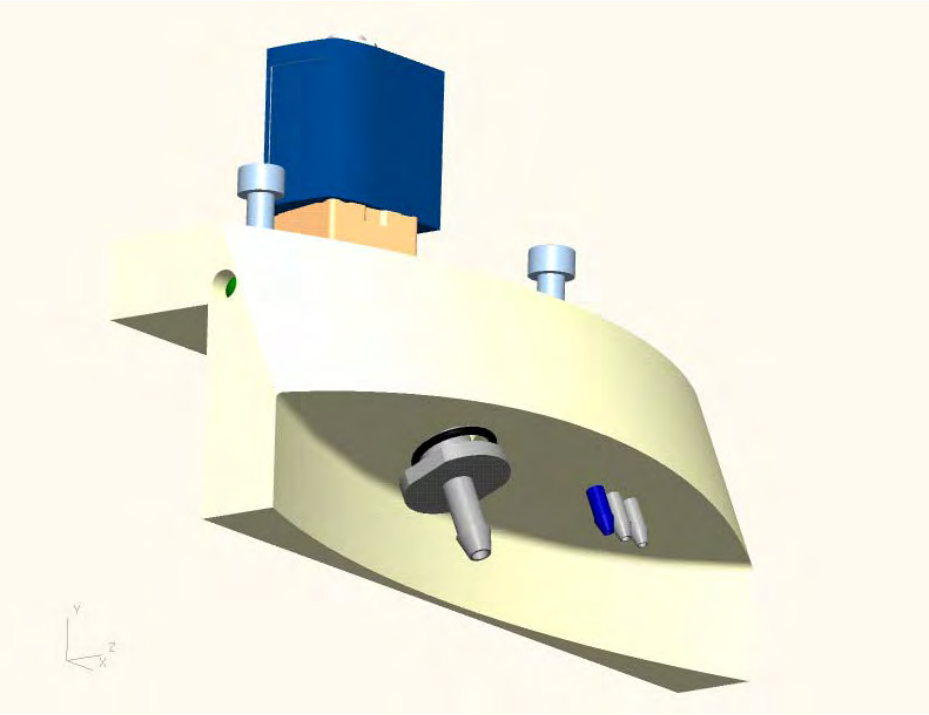


Figure 4-24

4.12.1 Nebulizer Valve (SV4)

The flow required to drive the nebulizer system is developed by reservoir gas passing through nebulizer solenoid SV4. The nebulizer solenoid is a two-way, normally closed, valve. When nebulization is required SV4 is switched on during the inspiratory phase allowing gas flow to the nebulizer circuit.

4.13 Inspiration Electronic System

The Inspiration ventilator electronic system may be powered by one of three available electrical power sources. During operation the microprocessor drives and controls the ventilator's pneumatic breath delivery system and carries out continuous monitoring of breath delivery and system parameters. The system allows the operator to program required settings via the user interface control panel and encoder switch.

The electronic system is comprised of the following major component parts:

- Power Input Components
- Power Supply PCB
- Internal Battery Pack
- External DC Circuitry
- Power board
- Sensor board
- Motherboard
- Processor Board
- Graphic Board
- LCD
- Inverter
- DC Converter PCB (LS non Touch Screen models only)
- Lexan screen
- Encoder switch
- Mini Web Interface (Optional)
- Touch Screen (Optional)

Electronic System Schematic Diagram

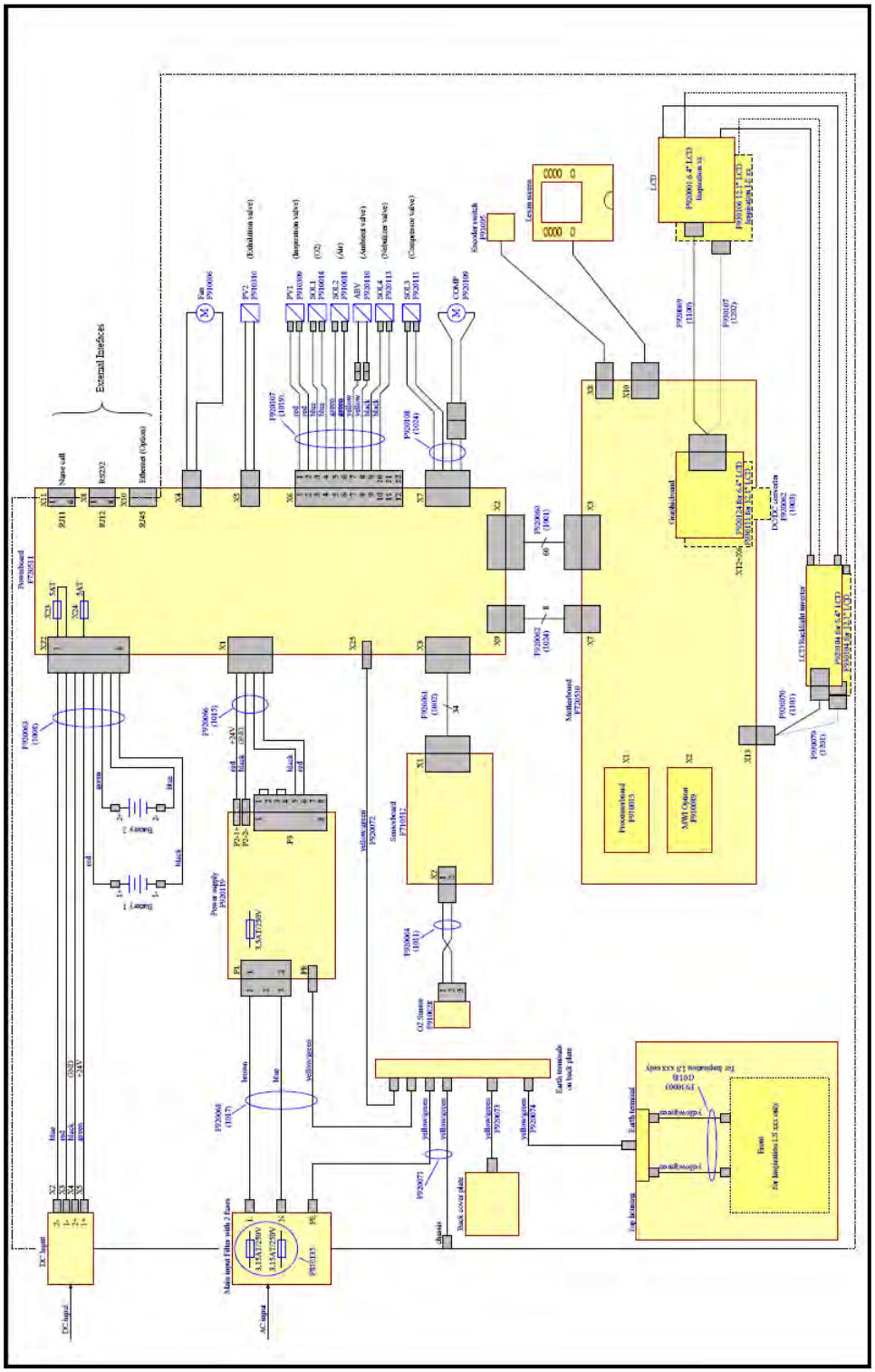


Figure 4-25

4.13.1 Power Input Components

The power input components of the Inspiration comprise of the ventilator power cord and a medical grade power inlet receptacle incorporating a line filter (Figure 4-26). The inlet filter is suitable to accommodate AC line voltages of 100-240VAC 50-60 Hz, and is fused at 2 x 3.15 amperes to accommodate both the high and low voltage ranges.

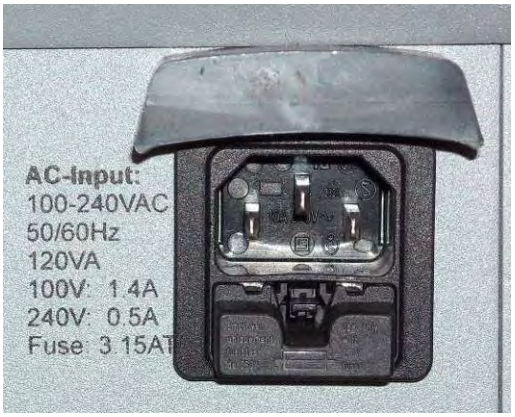


Figure 4-26

4.13.2 Power Supply PCB

The power supply is a medical grade high efficient supply with true auto ranging characteristics. It is rated for a supply voltage range of 100-240VAC 50/60 Hz. The power supply provides a single regulated 24VDC output routed to the Power board. Other voltages required for operation are generated at the Power board.

The power supply also incorporates power fail circuitry which provides an output signal to the power processor in the event of a loss, or decrease, in AC supply conditions (Figure 4-27).

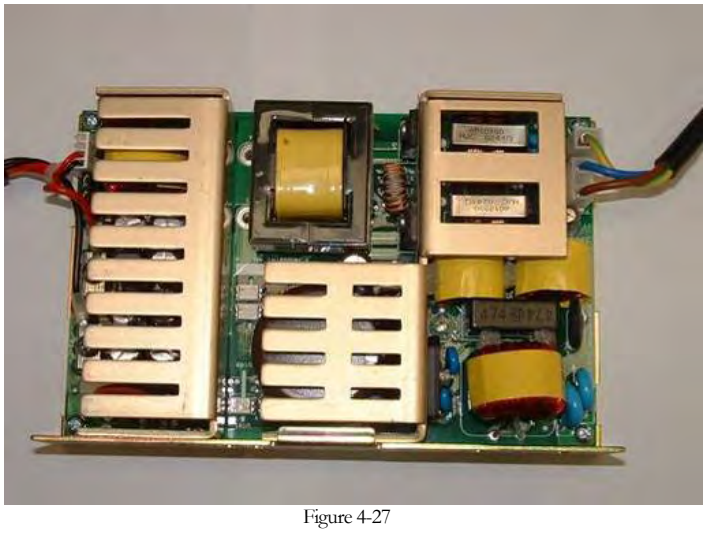


Figure 4-27

4.13.3 Internal Battery

In the event of a loss of the AC supply, the internal battery assembly (Figure 4-28) will provide temporary back-up power. Comprised of two 12VDC sealed lead-acid battery cells, connected serially at the Power board, the internal batteries provide a 24VDC back up supply.

The internal battery assembly on the Inspiration series ventilators is rated at 7.2 amp/hours. With a full charge the internal battery should sustain ventilator operation, with high pressure gas supplies and nominal settings in use, for ≥120 minutes. With the internal compressor in use the battery life is ≤120 minutes.

The manufacturer recommends that the internal battery assembly be replaced at a minimum interval of 24 months. Failure to follow this recommendation may compromise the availability of battery back-up. Any time it is plugged in and the AC supply is available the ventilator charges the internal battery assembly.

Caution:

The internal battery must be connected per the label provided on the inside of the battery compartment cover.

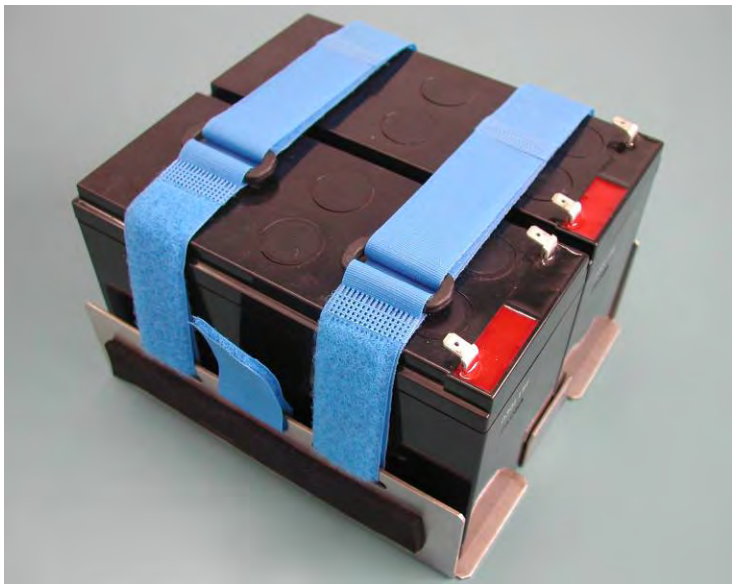


Figure 4-28

4.13.4 External Battery

To supplement the AC mains and the internal battery, the operator has the option of using an external 24VDC battery. An external DC receptacle is provided on the ventilators rear panel to allow connection of the external battery or external 24VDC power source (Figure 4-29).

Note:

The external battery is not charged by the ventilator; therefore an external battery charger must be used to recharge the external battery after use.

Figure 4-29

4.13.5 Power board

The Power board (Figure 4-30) is mounted vertically on the ventilators pneumatic chassis. A description of the critical functions of the Power board is described in the text below.

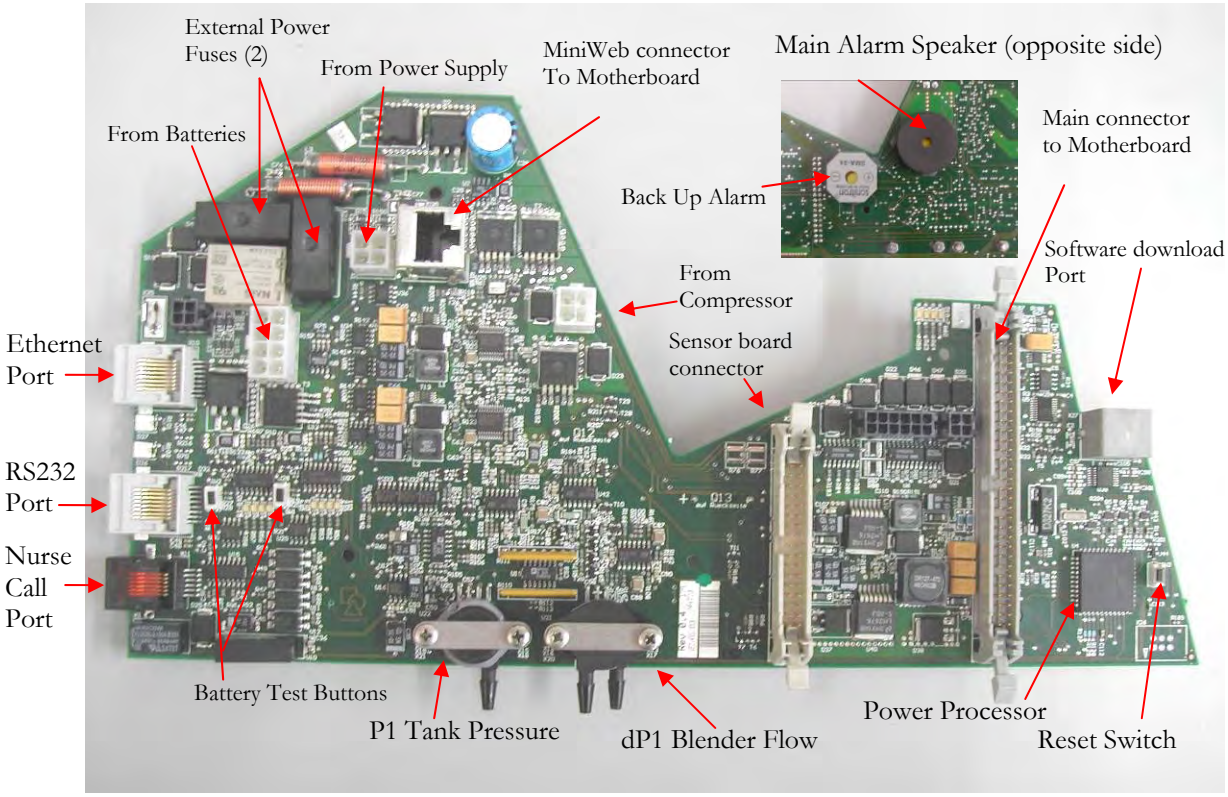


Figure 4-30

Power Software Storage

Resident on the Power board is a microcontroller with a flash EPROM which is used for storage of power system software. The software may be updated as necessary through the RS232 download port adjacent to the Power Processor chip.

Power Processor Reset

Adjacent to the power microcontroller is the power processor reset switch. This switch is used during the power software installation procedure and may also be used for troubleshooting (turning off the device).

Power Source Management

The power processor monitors the three available power sources at all times and controls the switching between them. The AC main always takes highest priority and powers the device whenever available. In the event AC mains are lost or unavailable the device attempts to switch to the external DC battery (if available) and then to the internal 24VDC battery.

The Power board is responsible for the internal battery charging and monitoring functions. The internal battery is under charge at all times when AC mains is connected to the ventilator, regardless of whether it is switched on or not.

Pneumatic Control

Circuitry located on the Power board is responsible for the control of all the valves within the pneumatic chassis. As signaled by the main microprocessor (located on the Processor Board) this circuitry switches the valves as required to control the breath delivery applications.

Blender Pressure Measurements

The Power board houses two pressure transducers, dP1 (blender flow sensor) and P1 (reservoir pressure) which are used to regulate operation of the blending system.

Input/Output Interfaces

The Power board houses interface circuitry for the three available interface circuits. The RS232, and Ethernet interfaces are standard RJ45 connectors and the nurse call connector is a standard RJ12 connector.

Main Processor Supervision

The power processor performs continuous monitoring and diagnostic checks on the device's main microprocessor located on the Processor Board. If it determines there is a problem which might compromise safe operation of the device it annunciates an error condition and places the device in a safety-valve-open condition.

4.13.6 Sensor board

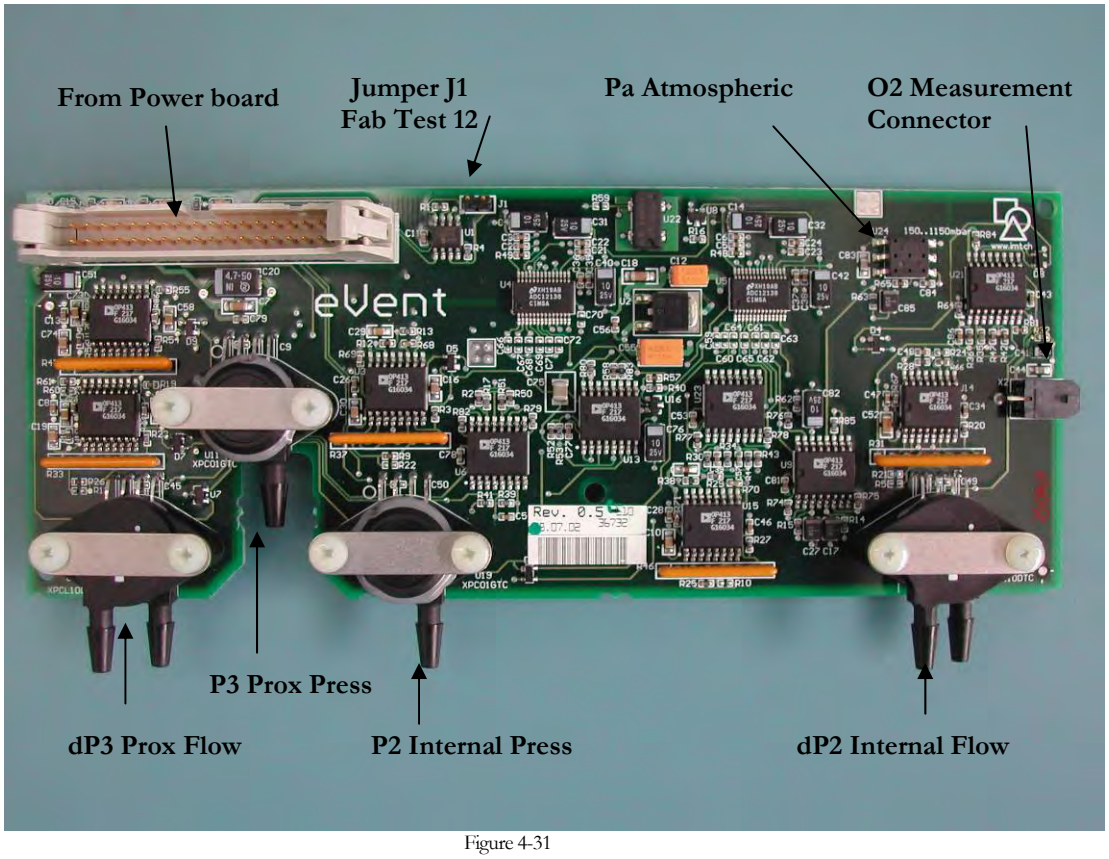


Figure 4-31

The Sensor board (Figure 4-31) is mounted vertically on the ventilator pneumatic chassis and provides feedback to the microprocessor during breath delivery. Incorporated on the Sensor board are four pressure transducers which are used for breath delivery, proximal measurements, and an interface circuit for the internal oxygen measurement system.

Breath Delivery Transducers

The Sensor board houses the two breath delivery (inspiratory) pressure transducers, dP2 (inspiratory flow sensor) and P2 (internal pressure) which are used to regulate the inspiratory proportional valve (PV1) during breath delivery.

Proximal Measurement Transducers

The Sensor board houses the two proximal pressure transducers, dP3 (proximal flow sensor) and P3 (proximal pressure) which are used to provide the microprocessor with feedback on patient exhaled gases.

Oxygen Sensor Interface

The ventilators integral oxygen sensor interfaces with electronic system through an interface circuitry on the Sensor board.

Barometric Pressure Transducer

The Sensor board incorporates a barometric pressure transducer which is used for appropriate correction of flow and pressure measurements.

A/D Converters

The analogue/digital converter circuitry on the Sensor Board is used to convert analogue information coming in from other areas of the electronic system (pressure transducers, temperatures, power supplies, etc) to a digital form as required by the microprocessor.

4.13.7 Motherboard

The Motherboard provides the primary interconnect and communications bus between the pneumatic chassis electronics, the Processor Board and the graphic module electronics (Figure 4-32).

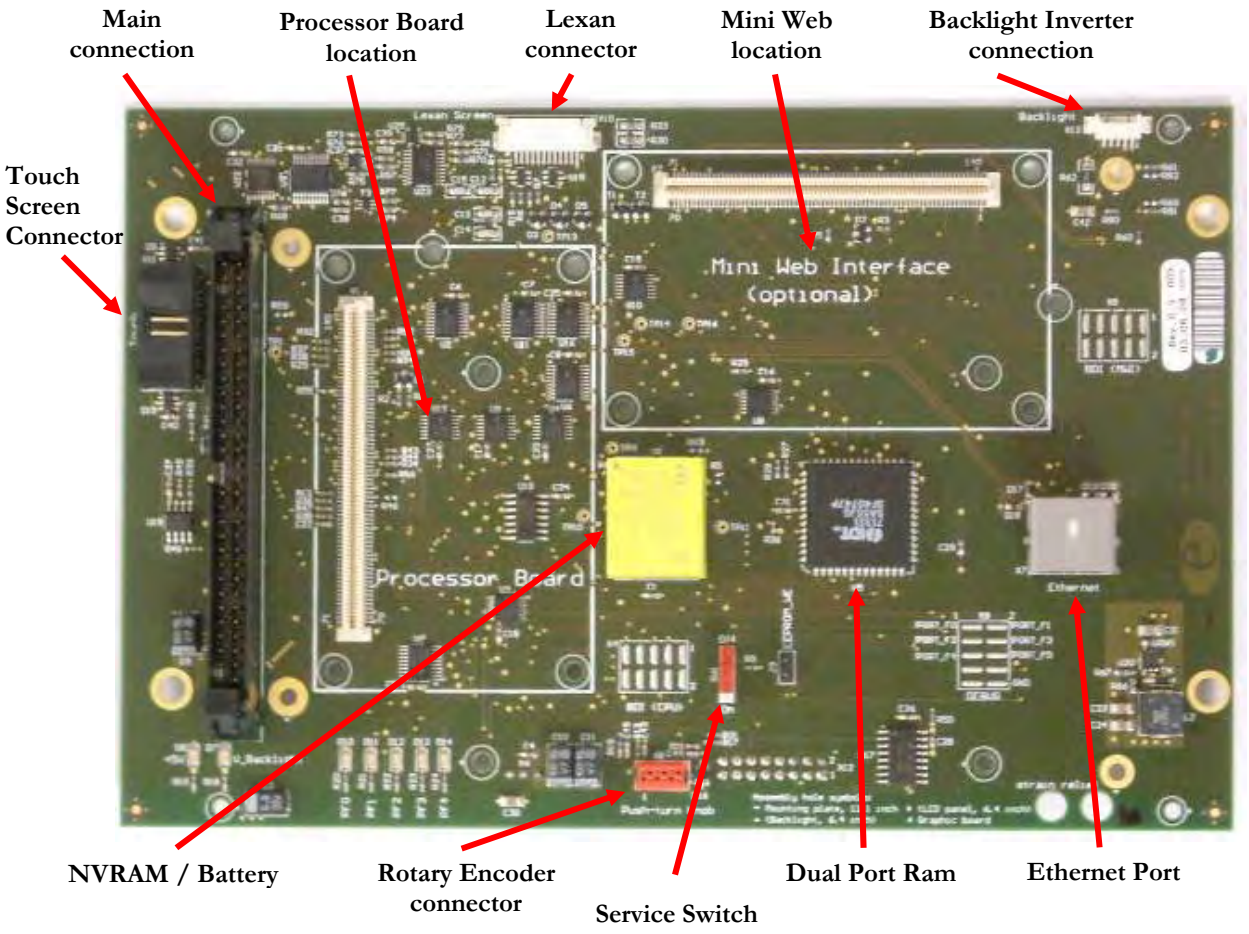


Figure 4-32

NVRAM

A Non-Volatile Random Access Memory device is included on this board for storage of critical information. The information stored in this location includes the following; ventilator and alarm settings, calibration look-up tables, date and time information, ventilator running hours, alarm and technical error logs, etc. The information is retained on this device by means of a replaceable lithium battery which has an approximate life of 10 years.

Dual Port RAM

A dual port RAM device is resident on the Motherboard and is used as a memory location to support the use of the mini web interface.

Service Switch

A slide switch is incorporated on the Motherboard and is used to default the device, on next power up, directly in to the service menu. This is typically used under fault conditions for troubleshooting purposes.

4.13.8 Processor Board

The Processor Board (Figure 4-33) provides overall control of all ventilator operations and breath delivery. It incorporates a microprocessor and associated circuitry which perform the following functions:

Figure 4-33

User Interface

Monitors and decodes the outputs from the front panel Encoder switch and the user interface hard keys. De-bounce circuitry is incorporated within this system to prevent inadvertent keystrokes on the front panel and Encoder switch.

Graphic Interface

The graphic interface circuit allows the microprocessor to interface with the Graphic Board in order to control the operation of the flat panel LCD.

Breath Delivery Control

The Processor Board interfaces with the pneumatic chassis electronics (Power board, Sensor board) in order to control all aspects of ventilation. The microprocessor receives continuous feedback (via the A/D converter on the Sensor board) from all of the transducers within the pneumatic system allowing it to regulate the operation of the pneumatic system.

Alarm Management

Circuitry within the Processor Board continuously compares operator set alarm limits with measurements received from the pneumatic system (via A/D converter), and elsewhere, to determine any violations of alarm criteria. In the event of an alarm criterion being met the microprocessor commands an alarm message be displayed with the appropriate level of visual and audible indication.

Power Processor Supervision

The main microprocessor performs a continuous monitoring and diagnostic check on the devices power processor located on the Power board. If it determines there is a problem which might compromise safe operation of the device it annunciates an error condition and places the device in a safety valve open condition.

4.13.9 Graphic Board

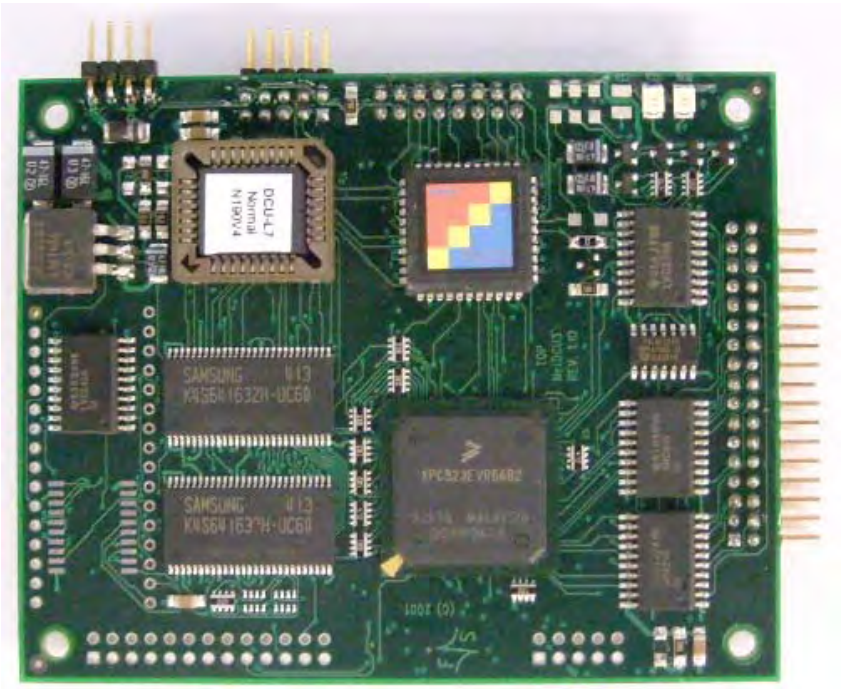


Figure 4-34

The Graphic Board (Figure 4-34) is mounted on the reverse side of the Motherboard. The Graphic Board drives the LCD assembly by means of an 8 bit parallel interface.

The Graphic Board receives display commands from the microprocessor which are processed locally into the required display format by means of an onboard 32 bit microcontroller.

The Graphic Board for the 12.1" and 6.4" models requires different hardware and software; therefore are not interchangeable.

4.13.10 User Interface Display

A single flat panel color LCD (Figure 4-35) is incorporated within the devices front panel in order to provide the user with ventilator settings and patient data. The Inspiration LS uses a 12.1" SVGA LCD panel whereas the Inspiration and Infant use a 6.4" VGA LCD panel. Each display includes dual CFL backlights which are driven by the backlight Inverter.

Figure 4-35

4.13.11 Backlight inverter

A backlight inverter is included in each Inspiration ventilator model (Figure 4-36). The inverter receives a single 12VDC from the Power board (via Motherboard). The inverter has dual outputs to drive the dual backlights used on the display of each ventilator. 12.1" and 6.4" displays require a dedicated model for each.

Figure 4-36

4.13.12 DC Converter PCB

The DC Converter PCB (Figure 4-37) is used solely in the Inspiration LS model (Non Touch Screen Only). The DC converter PCB receives a single 5 VDC input from the Graphic Board which must be converted to 3.3 VDC as required to drive the flat panel LCD for the Inspiration LS.

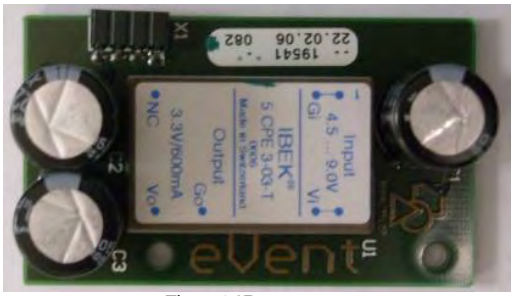


Figure 4-37

4.13.13 User Interface

Figure 4-38

The user interface Lexan screen incorporates a total of ten keys which permit the user to power the ventilator on/off, to select the active screen to be displayed on the LCD panel, and to enable various other functions. Additionally, the Lexan screen incorporates a red LED used to visually indication any alarm event, and a green LED used to indicate when AC power is applied to the device (Figure 4-38).

4.13.14 Encoder switch

The operation of the Encoder switch permits the operator to select and change ventilation modes and settings. The Encoder switch is a 16 position rotary encoder permitting navigation and adjustment of ventilator settings (Figure 4-39).

Figure 4-39

4.13.15 Mini Web Interface PCB (Optional)

The Mini Web Interface PCB is an optional device which when added to the system enhances the communications capabilities of the Inspiration ventilator system (Figure 4-40).

The mini web interface provides the user with a low cost remote viewing solution. The mini web interface allows the connection of any number of inspiration ventilators to a local area network for remote viewing. All forms of ventilator data; settings, patient monitored data, waveforms, alarms, etc., are accessible for viewing through this media. No remote adjustment of ventilator settings is possible through the mini web interface.

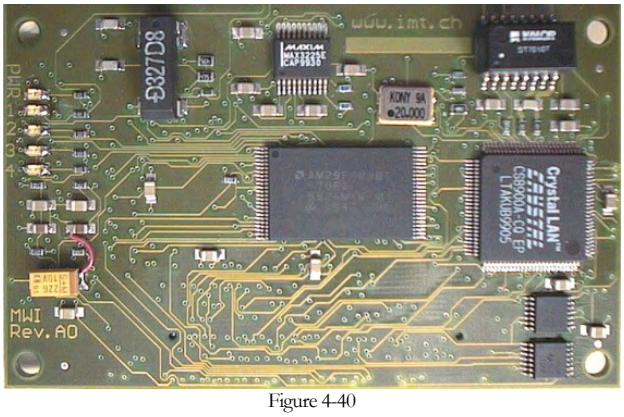


Figure 4-40

4.13.16 Touch Screen

Figure 4-41

The term touch screen refers to the front screen of the Inspiration ventilator. The touch screen is a pressure sensitive module mounted to the device's LCD (Figure 4-41). It consists of a resistive array embedded in two polymer planes. The ventilator constantly scans the array for resistive changes caused by compressing the two planes until they touch.

A touch screen enabled ventilator can be identified either of the following two ways:

1. The unit has a TS included in its part number.
2. In the upper left hand corner of all user and configuration screens there is a square with the letter T inside the square. A touch screen calibration must be performed once or this icon will not be displayed.

A periodically recalibration is normally not required thanks to the high quality 8 wire resistive technique used. However if the user sees a need to perform a recalibration it can be done at any time.

Section

5

SELF TEST AND CONFIGURATION SCREENS

5.1 Introduction

This section of the Inspiration Series Ventilator Technical Manual provides a detailed description of the ventilator's self-testing functions and the user configuration screens. Some troubleshooting information relevant to these self test functions is added for convenience at each stage.

5.2 Power On Self Test (POST)

Power On Self Test, or POST as it is commonly referred to, is performed each time the ventilator is switched on in all modes (User, Configuration, Service). Following switch on, the software loading/self test screen is displayed as shown in Figure 5-1. POST includes a numbers of tests which are structured so each consecutive test requires more and more hardware. Testing in this step by step way ensures a full and thorough check of ventilator system operation prior to use. The testing steps are performed as follows:

- POST Test 1: Tests external RAM components
- POST Test 2: Tests internal processor RAM
- POST Test 3: Tests for correctness of the program code in ROM used in flash memory locations
- POST Test 4: Tests the integrity of NVRAM data, A/D converter initialization, integrity of EPROM memory locations, etc.

In the event an error condition is detected during the power on self test, the device responds by attempting to place the device into a known state and by annunciating appropriate alarm messages.

Any failure during the early part of POST results in the power on process going no further than the self test screen, and is accompanied by a continuous audible alarm tone generated by the backup alarm.

Any failure detected during the later parts of POST results in the normal start up screen being displayed on the LCD screen. The self test field reports a TF (technical fault) error code specific to the problem detected and annunciates a high priority audible alarm, and visual display confirming the fault condition. In this case start of ventilation is not possible.

Figure 5-1

5.3 Troubleshooting Power On Self Test

In the event a problem is detected during the POST routines, the device displays an error code specific to the condition detected. The respective error codes along with a definition and troubleshooting recommendations are included in the Technical Error Listing and Troubleshooting: table (found in section 8 DIAGNOSTIC ERROR CODES and ALARM MESSAGES of this manual).

5.4 User Calibration

User calibration functions are provided on the Inspiration ventilator which allows the user to configure and check the ventilator prior to operating it. These functions may be accessed through the normal start up screen (Figure 5-2) by selection of the Calibrations option.

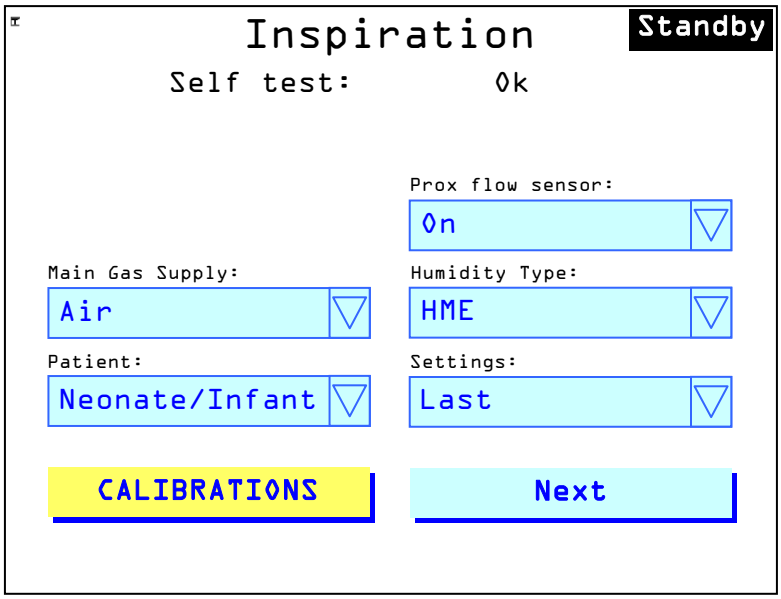


Figure 5-2

On selection of the calibrations menu the calibration screen (Figure 5-3) appears in the display area. Select System Test in order to view the pull down menu for all user calibrations. A detailed description for each calibration is included in this section.

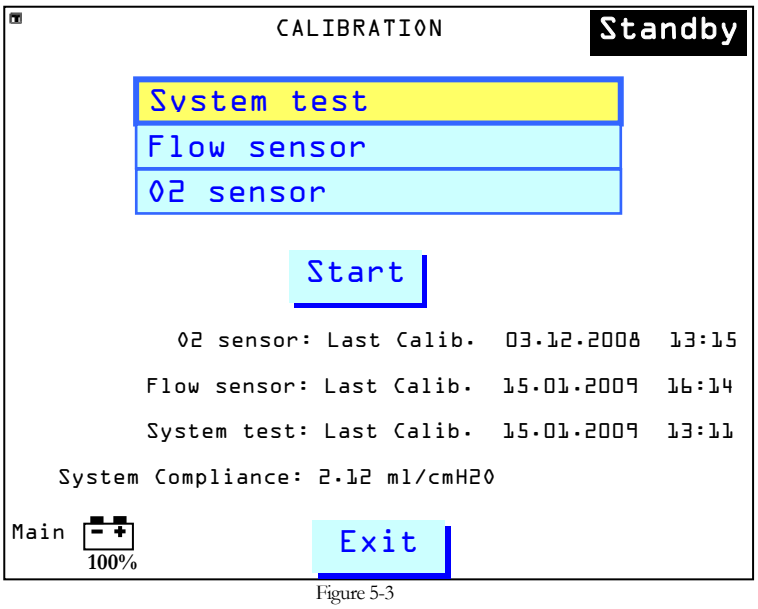


Figure 5-3

5.5 System test

System Test may be run by the user in order to verify the integrity of the patient tubing system components. Running the system test allows the operator to quantify any leakage from the patient tubing system prior to clinical patient use.

During the system test the device also quantifies the compliance characteristics of the patient tubing system. The calculated system compliance (ml/cmH_2O) will then be used on a breath by breath basis to compensate for circuit effects and ensure that volume delivery and measurements are maintained to specification.

The manufacturer recommends the system test is performed routinely between patients and when the patient tubing system or components thereof are replaced or modified. Failure to perform system test as required may lead to leaks or incorrect compliance factors influencing breath delivery and monitoring functions.

During the first part of system test the device exercises the inspiratory proportional valve (PV1) to ensure it opens fully. Once the proportional valve is exercised, the device checks to see the reservoir pressure (P1) remains below 100cmH_2O pressure. Failure at this stage results in an emptying tank error accompanied by an appropriate error number. On successful completion of this first test the device recharges the reservoir for the next steps.

Next, with zero flow conditions, the device performs a re-zero for all of the transducers which are used for the calibration. Internal flow sensor (dP2) and internal pressure sensor (P2) are also zeroed prior to being used for the calibration.

On completion of this step the device displays a message in the test progress field prompting the user to block wye. The user should block the wye with an appropriate stopper then confirm to proceed.

Once the device receives this confirmation PV2 is closed, and PV1 is opened to deliver a flow of 6 l/min into the patient system. As the system pressure passes 10cmH_2O compliance flow detection starts, and the pressure continues to rise to a target of 50cmH_2O. Once this pressure is reached PV1 is closed and PV2 remains closed.

After a short stabilization period (approx 1 second), the device holds the system closed for 4 seconds during which it monitors the pressure drop at P2. The test passes if the leakage detected is less than or equal to 3cmH_2O/second. If the leakage falls outside this range the test fails and a fault specific error code is displayed.

Note:

The system test may be performed using either external high pressure gasses or using the internal compressor system.

5.6 Flow sensor Calibration

Flow sensor calibration is run by the user in order to define the performance characteristics of the proximal flow sensor prior to use. The calibration data derived during this procedure is stored in NVRAM and used during normal operation to ensure accurate proximal measurements.

The manufacturer recommends that flow sensor calibration is performed routinely prior to use; between patients and at all times following its replacement or sterilization. Failure to perform proximal flow sensor calibration as required may lead to inaccuracies in exhaled volume measurements (Vte), and problems with flow triggering characterized by insensitivity or auto triggering.

During the first part of flow sensor calibration the device exercises the inspiratory proportional valve (PV1) to ensure it opens fully. Once the proportional valve is exercised, the device checks to see the reservoir pressure (P1) remains below 100cmH_2O pressure. Failure at this stage results in an emptying tank error accompanied by an appropriate error number. On successful completion of this first test the device recharges the reservoir for the next steps.

Next, with zero flow conditions, the device performs a re-zero for all of the transducers which are used for the calibration. Internal flow sensor (dP2), internal pressure (P2), proximal flow sensor (dP3) and proximal pressure (P3) are zeroed prior to being used for the calibration.

Next the inspiratory valve (PV1) is opened to deliver a flow of 30 l/min into the patient tubing system and through the proximal sensor located at the wye. The flow passing through the proximal element (FS3) results in a proportional differential pressure reading internally at transducer dP3. The microprocessor assesses the reading and the resultant gain to determine that it is within limits, and which limit it falls within; Adult/Pediatric or Infant/Pediatric. If the values fall within limits the calibration proceeds to the next stage. If the values fall outside of both ranges or if some other issue is detected the calibration terminates and displays an appropriate error message.

During the next part of the procedure the device checks the characteristics at a second lower flow value. If the values seen in the previous step are found to fall within Pediatric /Infant limits a flow of 6 l/min is used for this calibration. If the values seen in the previous step are found to fall within Adult/Pediatric limits a flow of 10 l/min is used for this calibration.

The inspiratory valve (PV1) is opened to deliver the second lower flow into the patient tubing system and through the proximal sensor at the wye. The microprocessor assesses the reading at dP3 and associated gain to determine if it is within limits. In the event that readings are within limits this step and the calibration as a whole passes. In the event that readings at this stage are outside of limits an error code specific to the stage and the nature of the problem detected is displayed on screen.

Note:

Proximal flow sensor calibration requires the use of at least one external high pressure gas source.

5.7 O2 sensor Calibration

Oxygen sensor calibration is run by the user in order to define the performance characteristics of the internal oxygen sensor prior to use. The calibration data derived during this procedure is stored in NVRAM and used during normal operation to ensure accurate measurement of the patient inspired FiO_2 level.

The manufacturer recommends that oxygen sensor calibration is performed routinely between each patient use and following replacement of the oxygen sensor or Sensor board. Failure to perform oxygen sensor calibration as required may lead to inaccuracies in the monitored oxygen percentage.

The device performs a two point calibration procedure using 100% oxygen and then 21% oxygen. The inspiratory valve (PV1) is opened to deliver a flow of approximately 10 l/min into the patient system. As the open PV1 draws gas from the reservoir the blending system refills it to maintain the required oxygen concentration.

Starting with 100% oxygen the device allows a period of time for the reservoir's oxygen concentration to stabilize and then a further period to allow the sensor reading to stabilize. On completion the microprocessor compares the reading and associated gain against limits. If the reading falls outside of limits the calibration stops and a specific error code is displayed. If the reading falls within limits the process is repeated for 21% oxygen.

Note:

Oxygen sensor calibration requires the use of a high pressure oxygen supply and an air supply (internal compressor or external high pressure air.)

5.8 Troubleshooting Self Tests

With the completion of each individual calibration, the calibration screen is updated with the pass or fail status for each, and a time and date stamp (international date dd.mm.yyyy and time hh:mm format) for each to indicate when it is completed as shown in Figure 5-4

Self test errors are displayed on the screen in the area between the test and start fields and also in the lower half of the screen in the test results area, also as shown in Figure 5-4. The respective error codes and messages, a definition there of, and possible steps for resolution are listed in Section 5.9 below.

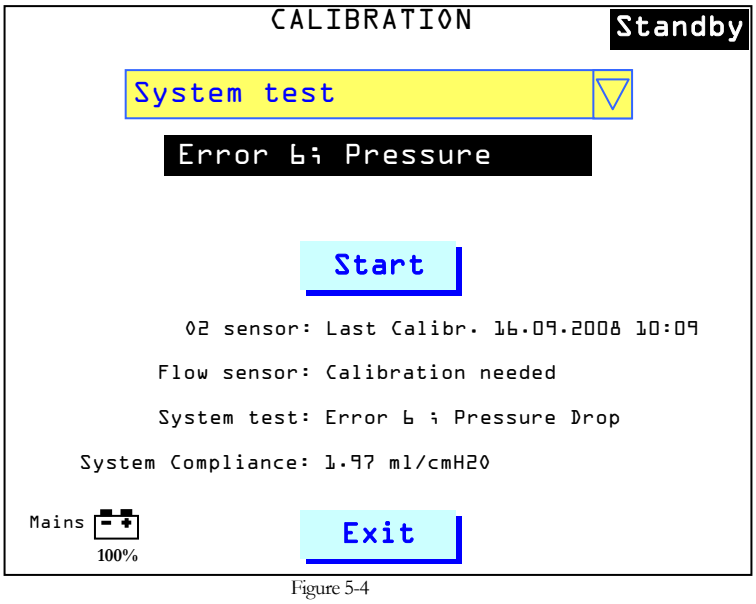


Figure 5-4

5.9 Troubleshooting Table

System Leak Test		
Error	**Definition**	**Suggested Solution**
Error 6 – Pressure Drop	Excessive Pressure Drop During System Test	1. Ensure closed patient system. 2. Ensure the exhalation membrane is installed correctly and undamaged. 3. Inspect the exhalation cover for damage. 4. Run system test with single tubing limb connect between outlet & exhalation cover. 5. Remove system tubing and verify flow from PV1. 6. Replace Sensor board.
Error 7 – Pressure Rise	Excessive Pressure Increase During System Test	1. Forward leak through PV1 valve. 2. Forward leak through Solenoid 4 if nebulizer is connected. 3. Replace Sensor board.
Error 8 – Max Time To Pressure	Unable To Adequately Pressurize Patient System	1. Ensure closed patient system. 2. Ensure the exhalation membrane is installed correctly and undamaged. 3. Inspect the exhalation cover for damage. 4. Run system test with single tubing limb connect between outlet & exhalation cover. 5. Remove system tubing and verify flow from PV1 6. Replace Sensor board
Error 10 – Deviation High	Flow At Transducer dP2 Out Of Range	1. Perform a manual re-zero of pressure transducers using FabTest 5 2. Verify internal flow sensor calibration, recalibrate as necessary.
Error 11 – Error Emptying Tank	Tank Pressure Remains Above 100mbar	1. Ensure that patient wye is open at the beginning of system test. 2. Verify that there is no leakage through blender module into reservoir. 3. Verify that PV1 is opening and flow is evident from the patient port. 4. Replace Power board. 5. Replace proportional valve PV1.
Error 12 - Emptying tank	Tank Pressure Remains > 100mbar	1. Ensure the patient wye is open at the beginning of system test 2. Verify that there is no leakage through blender module into reservoir 3. Verify that PV1 is opening and flow is evident from the patient port 4. Replace Power board. 5. Replace Inspiration valve PV1

System Leak Test		
Error 13 - Deviation high	Error in compliance calculation of patient system	1. Ensure closed patient system

Flow Sensor Calibration		
Error 12 – High Pressure	Pressure Out Of Range	1. Ensure the proximal sensor is connected to the tubing system and that its outlet is open. 2. Replace proximal sensor 3. Verify internal flow sensor calibration, recalibrate as necessary. 4. Verify PV1 calibration, recalibrate as necessary.
Error 13 – Deviation High	Failure during re-zero of dP2	1. Perform a manual re-zero of all pressure transducers using FabTest 5. 2. Replace Sensor board
Error 14 – Deviation High	Failure during re-zero of dP3	1. Perform a manual re-zero of all pressure transducers using FabTest 5. 2. Replace Sensor board
Error 15 – Deviation High	Failure during re-zero of dP3 high gain	1. Perform a manual re-zero of all pressure transducers using FabTest 5. 2. Replace Sensor board
Error 16 – Deviation High	Failure during re-zero of P3	1. Perform a manual re-zero of all pressure transducers using FabTest 5. 2. Replace Sensor board
Error 17 – Deviation High	Differential pressure at dP3 too low at high flow	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Re-zero pressure transducers using FabTest 5. 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor board
Error 18 – Deviation High	Differential pressure at dP3 at high flow between infant/adult ranges.	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Re-zero pressure transducers using FabTest 5. 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor board

Flow Sensor Calibration		
Error 19 – Deviation High	Differential pressure at dP3 too high at high flow	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Re-zero pressure transducers using FabTest 5. 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor board
Error 20 – Deviation High	Differential pressure at dP3 too low at low flow	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Re-zero pressure transducers using FabTest 5. 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor board
Error 21 – Deviation High	Differential pressure at dP3 too high at low flow	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Re-zero pressure transducers using FabTest 5. 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor board
Error 22 – Deviation High	Coefficient (a) too low	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace Proximal Sensor 4. Re-zero pressure transducers using FabTest 5. 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor board

Flow Sensor Calibration		
Error 23 – Deviation High	Coefficient (a) too high	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace Flow Sensor. 4. Re-zero pressure transducers using FabTest 5. 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor board
Error 24 – Deviation High	Coefficient (b) too low	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace Flow Sensor. 4. Re-zero pressure transducers using FabTest 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor board
Error 25 – Deviation High	Coefficient (b) too high	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, FabTest 5 5. Verify internal flow sensor calibration, recalibrate as necessary.
Error 26 – Saving Data	NVRAM Damaged – Unable to save calibration data to NVRAM	1. Replace proximal sensor 2. Perform NVRAM test 3. Clear & Test NVRAM, recalibrate device. 4. Replace Motherboard
Error 27 – Emptying Tank	Error Emptying Tank – Pressure remains > 100 mbar	1. Ensure that patient wye is open at the beginning of flow sensor calibration. 2. Verify that there is no leakage through blender module into reservoir. 3. Verify that PV1 is opening and flow is evident from the patient port. 4. Replace proportional valve PV1.
Error 28 – Low Pressure	Pressure P2 < 15 mbar	1. Perform system test to ensure that there is no leakage from the system. 2. Ensure that the wye is blocked as prompted. 3. Replace proximal flow sensor 4. Perform calibration of proportional valve PV1.

Flow Sensor Calibration		
Error 29 – High Pressure	Pressure P2 > 40 mbar	1. Replace proximal flow sensor 2. Perform calibration of proportional valve PV1
Error 30 – Deviation High	Flow for dynamic calibration too high	1. Perform system test to ensure that there is no leakage from the system. 2. Replace proximal flow sensor 3. Replace Sensor board
Error 31 – Deviation High	Dynamic calibration coefficients not ok	1. Perform system test to ensure that there is no leakage from the system. 2. Replace proximal flow sensor
Error 32 – Air Supply	No air supply available	1. Verify that an adequate high pressure air source is available and connected to the device. 2. Perform visual inspection of inlet check valves. 3. Verify operation of the blending system.
Error 33 – Deviation High	Differential pressure at dP3 high flow high gain too low	1. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 2. Replace proximal sensor 3. Re-zero pressure transducers using FabTest 5. 4. Verify internal flow sensor calibration, recalibrate as necessary. 5. Replace Sensor board
Error 34 – Deviation High	Differential pressure at dP3 high flow high gain too high	1. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 2. Replace proximal sensor 3. Re-zero pressure transducers using FabTest 5. 4. Verify internal flow sensor calibration, recalibrate as necessary. 5. Replace Sensor board
Error 37 – Deviation High	Co-efficient A – High Gain too low	1. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 2. Replace proximal sensor 3. Perform re-zero of pressure transducers, FabTest 5 4. Verify internal flow sensor calibration, recalibrate as necessary.
Error 38 – Deviation High	Co-efficient A – High Gain too high	1. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 2. Replace proximal sensor 3. Perform re-zero of pressure transducers, FabTest 5 4. Verify internal flow sensor calibration, recalibrate as necessary.

Flow Sensor Calibration		
Error 39 – Deviation High	Co-efficient B – High Gain too low	1. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 2. Replace proximal sensor 3. Perform re-zero of pressure transducers, FabTest 5 4. Verify internal flow sensor calibration, recalibrate as necessary.
Error 40 – Deviation High	Co-efficient B – High Gain too high	1. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 2. Replace proximal sensor 3. Perform re-zero of pressure transducers, FabTest 5 4. Verify internal flow sensor calibration, recalibrate as necessary.
Error 43 - Wrong sensor type	No Infant sensor type detected for an Inspiration *infant* only device	1. Ensure that an Infant type proximal flow sensor is connected 2. Replace proximal flow sensor
Oxygen Sensor		
Error 2 – Saving Data	NVRAM Damaged.	1. Replace O_2 Sensor 2. Perform NVRAM test **Note: Do Not Clear NVRAM if test passes.** 3. Clear & Test NVRAM, recalibrate device. 4. Replace Mother board
Error 3 – Deviation High	Error during calibration at 100% setting.	1. Ensure O_2 supply is connected and adequate flow available. 2. Ensure O_2 Sensor connected correctly. 3. Replace O_2 Sensor. 4. Confirm that inlet check valves CV1/2 are correctly installed and undamaged, replace as necessary. 5. Replace Sensor board. 6. Replace O_2 Sensor interface block.
Error 4 – Deviation High	Error during calibration at 21% setting.	1. Ensure Air supply is connected and that adequate flow is available, or that internal compressor is available and running. 2. Ensure O2 Sensor connected correctly. 3. Replace O2 Sensor. 4. Confirm that inlet check valves CV1/2 are correctly installed and undamaged, replace as necessary. 5. Replace Sensor board. 6. Replace O2 Sensor interface block.

Flow Sensor Calibration		
Error 8 – Sensor Not Available	Oxygen sensor is not available for calibration.	1. Enter configuration screen 1 and ensure that the oxygen sensor is enabled. 2. Open oxygen sensor compartment and ensure that it is installed and properly connected.
Error 9 – Oxygen Not Available	Oxygen supply not available for calibration	1. Ensure Oxygen supply is connected and that adequate flow is available. 2. Confirm the inlet check valves CV1/2 are correctly installed and undamaged, replace as necessary. 3. Confirm operation of the oxygen solenoid (SV1), replace as necessary.

5.10 User Configuration Screens

The user configuration mode allows the user to configure a number of performance attributes to their desired settings.

Figure 5-5

5.11 Configuration Mode Entry

To switch the device on in the configuration mode, press and hold the Special key and the press and hold On/Off key as indicated in Figure 5-5. Keep these two buttons pressed throughout the Power On Self Test (POST.) On successful completion the configuration screen is displayed. See Figure 5-6.

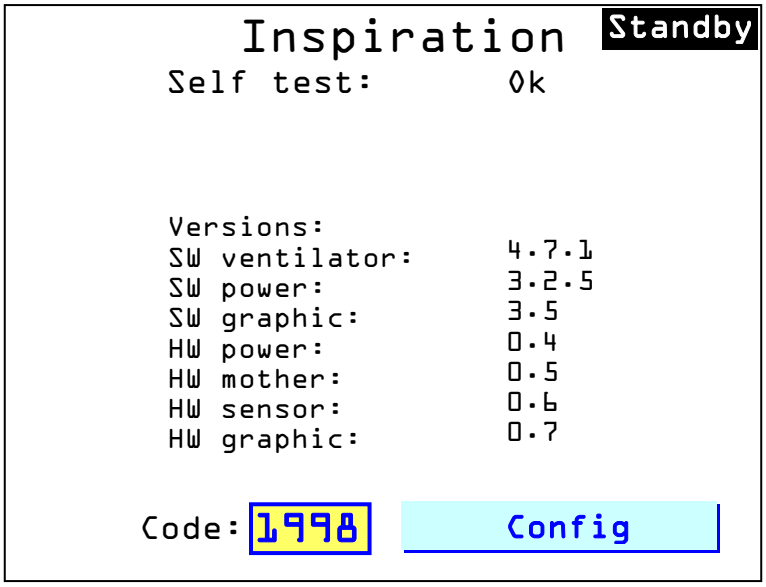


Figure 5-6

Navigate to the code entry field and enter the default code of 1998. Select Config and the device displays configuration screen 1.

5.12 Configuration Screen 1

Configuration screen 1 (Figure 5-7) allows the operator to configure attributes specific to how the ventilator operates and is monitored during normal ventilation. The attributes which may be adjusted are defined below:

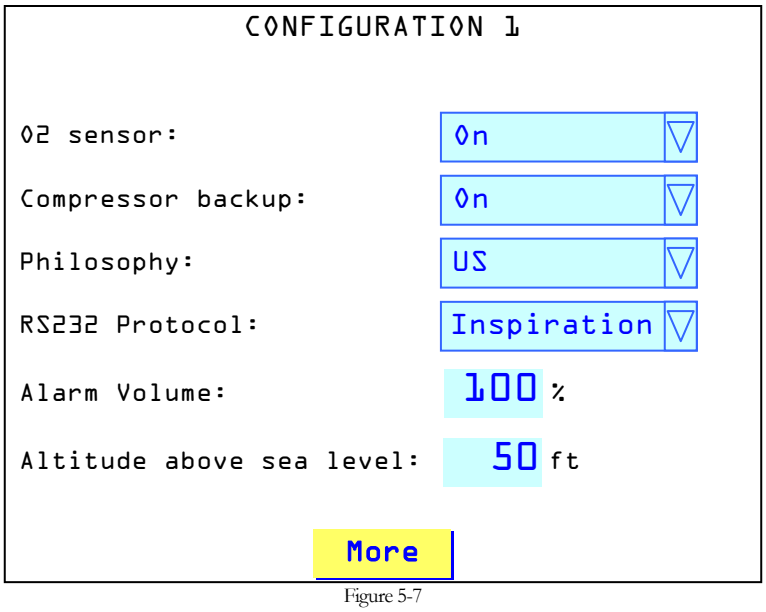


Figure 5-7

5.12.1 Proximal Flow Sensor (Not shown*)

Allows the user to enable or disable proximal flow measurement. With the flow sensor On patient monitored data is derived from the proximal flow element. With the flow sensor Off monitored data is derived from internal transducers and flow triggering is disabled.

* **Note:** on later versions of software this configuration option is found on the Standby screen.

5.12.2 O_2 Sensor

Allows the user to enable or disable the internal oxygen measurement cell. With the oxygen sensor disabled all oxygen monitoring and associated alarms is disabled. Once enabled the oxygen sensor must be calibrated.

Note:

The O_2 sensor does not control air and oxygen mixing. It is used for monitoring only therefore correct air and oxygen mixtures are not affected when the sensor is disabled.

5.12.3 Compressor Back Up

Allows the user to enable or disable the internal back up compressor. This is only available if an internal backup compressor is installed.

5.12.4 Buzzer / Alarm Volume

Allows the user to adjust the volume of the main alarm speaker between 35-100%.

5.12.5 Philosophy

Allows the user to configure the philosophy by which breath parameters are programmed on the device. US and European philosophy are available.

With European philosophy selected breath timing is governed by the I:E ratio control in volume and pressure based breaths. With US philosophy selected breath time is governed by the peak flow control in volume ventilation and by the inspiratory time control in pressure ventilation modes.

5.12.6 Altitude Above Sea Level

Allows the operator to set the approximate altitude at which the device is operating. This value must be set on first installation of the product. The value entered here has an influence to all flow and volume calculations made in the ventilator.

5.13 Configuration Screen 2

Configuration screen 2 (Figure 5-8) allows the user to configure some of the ventilators more general attributes. The attributes which may be configured in this way are defined below.

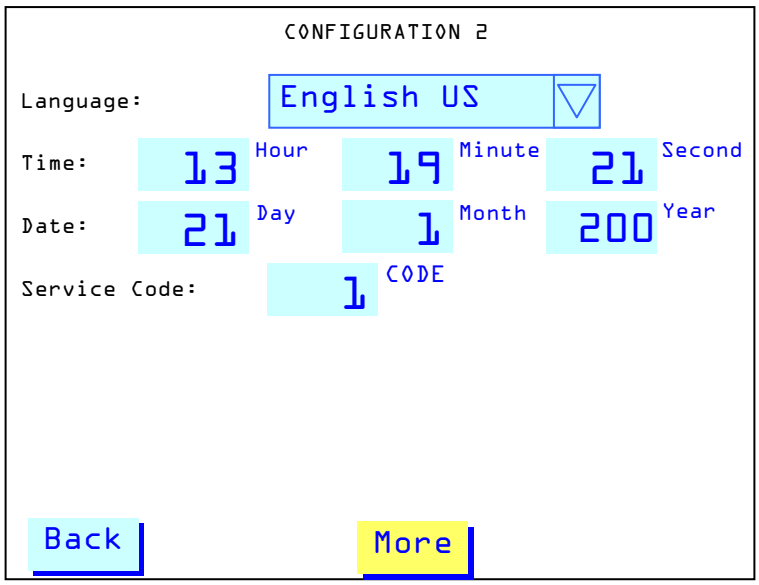


Figure 5-8

5.13.1 Language

Allows the user to configure the language which is used on the user display interface during normal operation. Languages which may be configured in this way are as follows:

Note:

Some Languages are not available with all software revisions.

Note:

The name of the language is showed in its native style to make identification easier. e.g. Españiol for Spanish

- English US
- German
- Italian
- Portuguese
- Russian
- Chinese
- English Int'l
- French
- Spanish
- Polish
- Japanese

5.13.2 Time

Allows the user to set the device real time clock to local requirements. Setting the time correctly ensures the accuracy of records maintained within the alarm and settings logs.

5.13.3 Date

Allows the user to set the current date for the real time clock. Setting the date correctly will ensure the accuracy of records maintained within the alarm and settings logs.

5.13.4 Service Code

Allows the user to define an access code for use during entry to the configuration menu. The default (1998) is always maintained as a backup entry code.

5.14 Configuration Screen 3

Configuration screen 3 (Figure 5-9) permits the operator to configure the necessary attributes which allow the device to be connected, via the MiniWeb™ interface, to a local area network (LAN) or via direct connection to a PC. The necessary attributes are detailed below. Please see MiniWeb Manual for more detailed instructions.

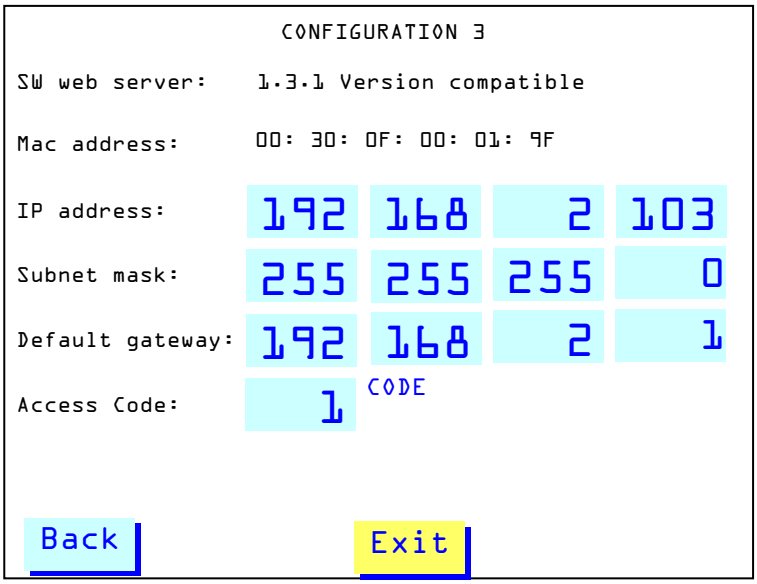


Figure 5-9

Note:

Configuration screen 3 will only be accessible if the MiniWeb interface (MWI) is installed on the device and has a compatible MWI software version installed

5.14.1 SW Web Server

This display indicates the current system software version installed to the MiniWeb server. Also provides an indication of whether the current MiniWeb and ventilator software versions are compatible.

5.14.2 Mac Address

This display indicates the defined Mac address (in Hex format) for the MiniWeb interface. This may be required by a network administrator to complete access to the device through a LAN.

5.14.3 IP Address

Allows the user to assign the device with a unique fixed IP address required to facilitate remote connection to the MiniWeb interface. DHCP functionality with dynamically assigned IP address is not supported.

5.14.4 Subnet Mask

Allows the user to assign the device a subnet mask address required to facilitate remote connection to the MiniWeb interface. This mask setting should be given by a network administrator.

5.14.5 Default Gateway

Allows the user to assign the device a default gateway address required to facilitate a remote connection to the MiniWeb interface. This address should be given by a network administrator.

5.14.6 Access Code

Allows the user to define and access code used when making remote connection to the MiniWeb interface.

Section

6

SERVICE MODE / FABTESTS

6.1 Introduction

This section of the Inspiration series technical manual is intended to provide the training service technician with details of how to access and use the fabrication (service) screens as a means of testing and troubleshooting the device.

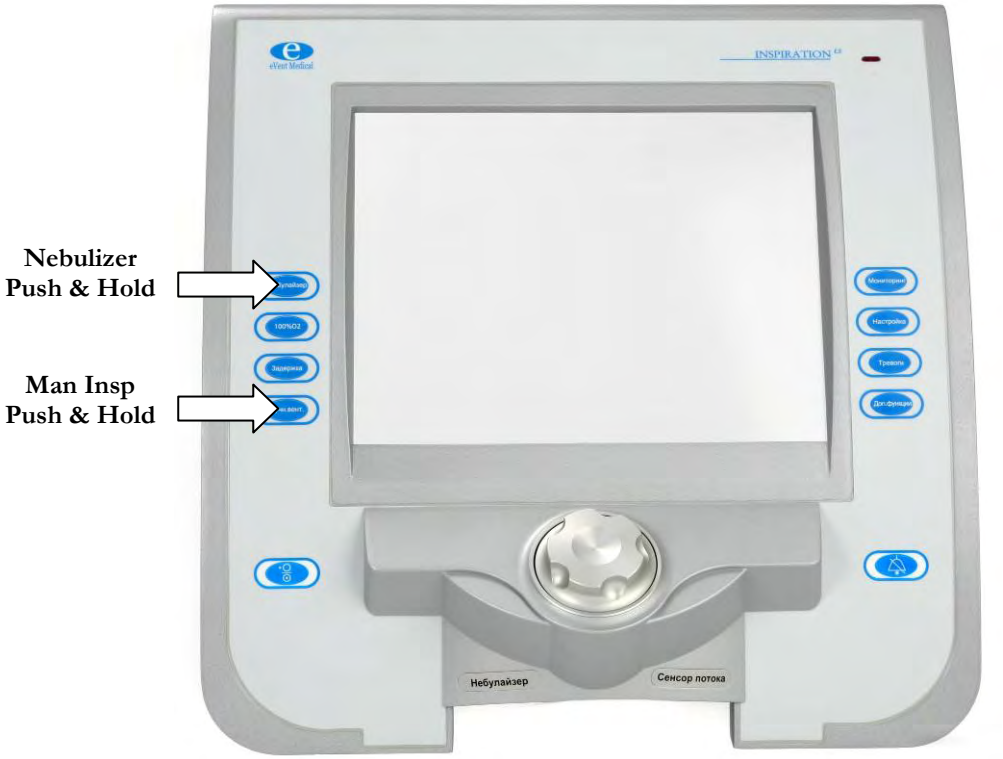


Figure 6-1

6.2 Accessing and Navigating Fabrication and Service Screens

The fabrication (service) screens are accessed by firstly switching the ventilator on. During the course of POST press and hold in the Nebulizer and Manual Inspiration keys (Figure 6-1), keep the buttons pressed in until POST completes and FabTest start up screen (Figure 6-2) is shown in the display area.

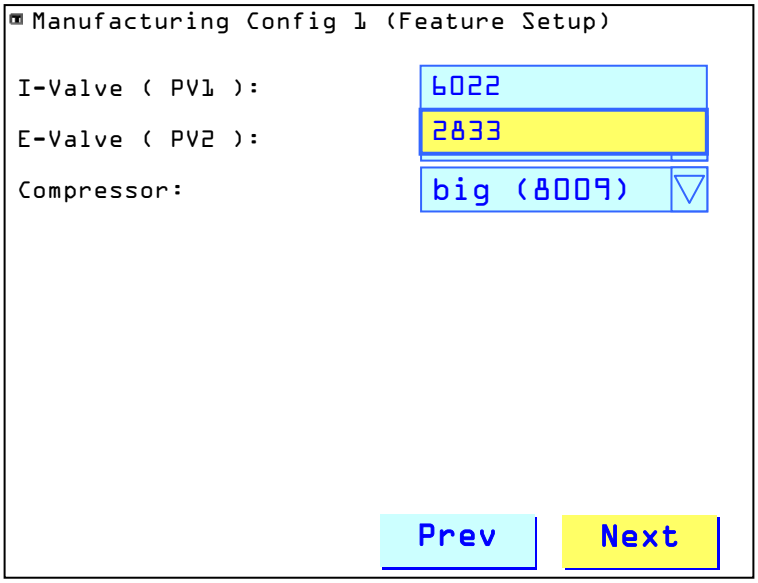


Figure 6-2

6.3 Overview of Manufacturing Configuration Screens

The manufacturing configuration screens allow the service technician to configure the device's hardware characteristics following service. The manufacturing configuration screens may be accessed from the FabTest start up screen. Enter 3333 in the code entry field and proceed to the manufacturing configuration screen 1.

6.4 Manufacturing Configuration Screen 1

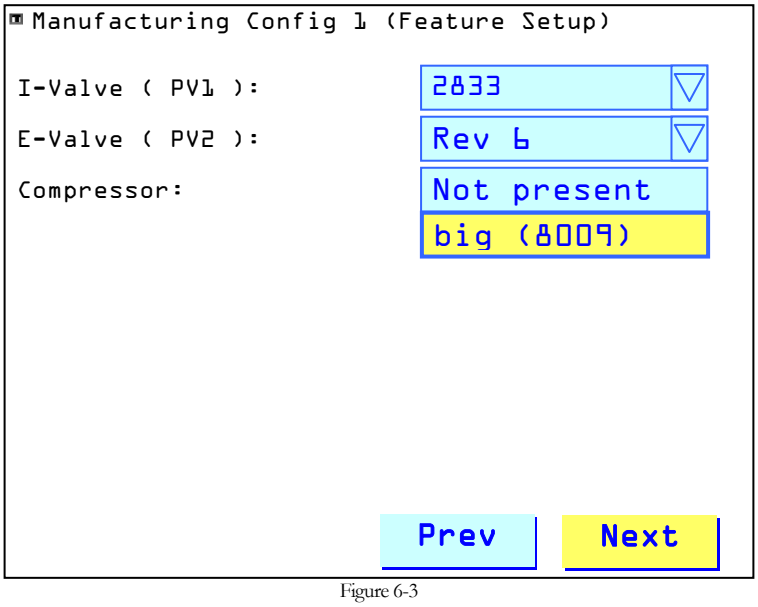


Figure 6-3

Manufacturing configuration 1 screen (Figure 6-3) allows the service technician to configure the following ventilator hardware characteristics:

6.4.1 I-Valve (PV1)

Allows the hardware version for the inspiratory valve (PV1) to be configured appropriately. May be set to either 6022 (earlier PV1 version) or 2833 (current PV1 version). With the setting made, the appropriate SW drivers for the selected valve is applied during breath delivery and the appropriate calibration procedure is enabled for FabTest 9. If in doubt, observe the labeling on the component itself in order to confirm the valve type.

6.4.2 E-Valve (PV2)

Allows the hardware version for the expiratory valve (PV2) to be configured appropriately. May be set to either 04/05 (earlier PV2 version) or 06 (current PV2 version). With the setting made, the appropriate SW drivers for the selected valve is applied during breath delivery. If in doubt, observe the labeling on the component itself in order to confirm the valve type.

6.4.3 Compressor

Allows the hardware version for the internal compressor to be configured appropriately. May be set to either None, if no internal compressor is installed, or 8009 if the current internal compressor is installed.

6.5 Manufacturing Configuration Screen 2

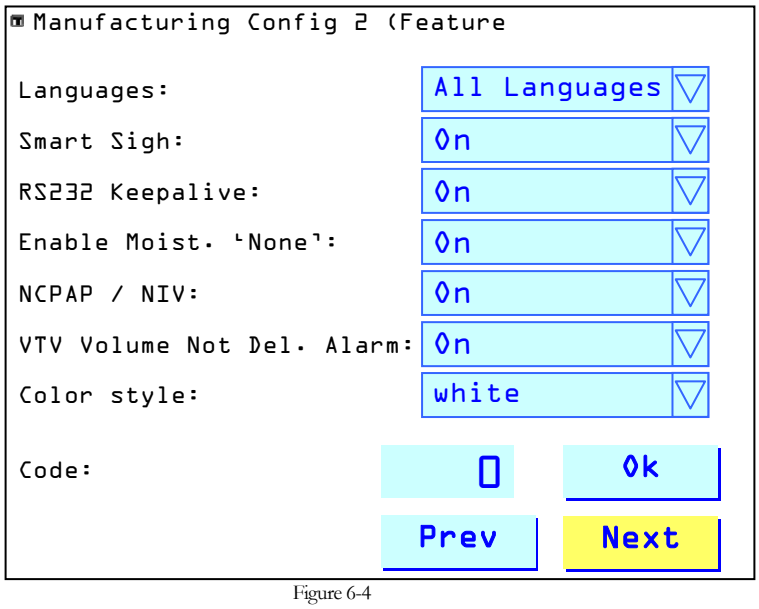


Figure 6-4

Manufacturing configuration 2 screen (Figure 6-4) allows the service technician to configure the following hardware characteristics on the device:

6.5.1 Languages

Allows the device to be configured with all available operating languages available or alternately English only.

6.5.2 Smart Sigh

Smart Sigh function may be selected On or Off.

6.5.3 RS232 Keep Alive

Allows continuous monitoring via the RS232 communications interface. When selected Off the communications will time out after an extended period of inactivity.

6.5.4 Enable Moisture None

Humidity type none may be selected On or Off. When selected On, the full list of humidity types are available to the user including None. None maybe useful for demonstration purposes using a mechanical test lung and no humidification corrections are needed

6.5.5 NIV/NCPAP

NIV and NCPAP function may be switched On or Off. When selected On, NIV (non-invasive ventilation) is available to the user with adult and Pediatric patient types selected. NCPAP (nasal continuous positive air pressure) is available to the user with infant patient type selected.

6.5.6 Code

The code entry field available in this screen enables access to configuration screen 3 which should only be accessed by eVent Medical trained service personnel.

6.6 Manufacturing Configuration Screen 3

6.7

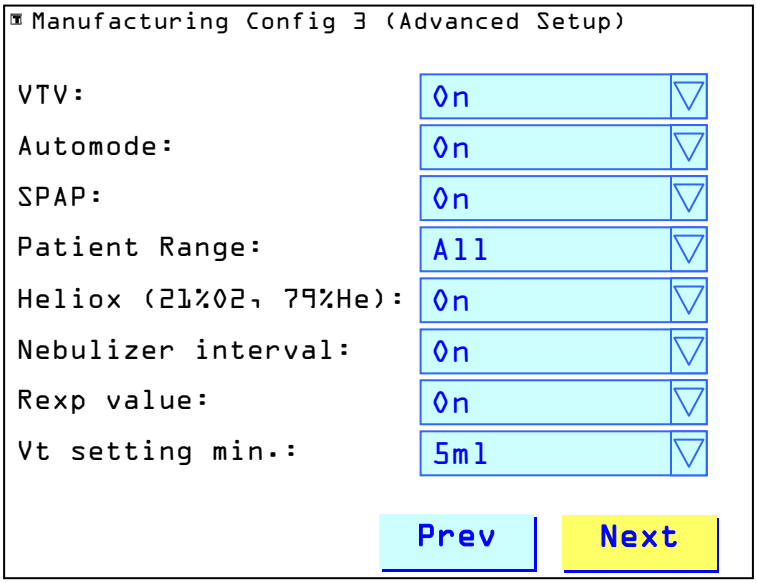


Figure 6-5

Manufacturing configuration 3 screen (Figure 6-5) is accessed by entering 6002 (8991 for older software revisions) in the code field of Configuration screen 2. It allows the service technician to configure the following features of the device:

6.7.1 VTV

Allows the device to be configured with Volume Targeted Ventilation.

6.7.2 Auto mode

Auto mode function may be selected On or Off.

6.7.3 SPAP

SPAP function may be selected On or Off.

6.7.4 Patient Range

Allows the device to be configured for All patient ranges or Infant Only.

6.7.5 Heliox

Heliox function may be selected On or Off. **Note:** This function has not been approved for use in the United States and should be selected off.

6.7.6 Nebulizer interval

Nebulizer interval function may be selected On or Off. **Note:** This function has not been approved for use in the United States and should be selected off.

6.7.7 Rexp value

Rexp value function may be selected On or Off.

6.7.8 Vt setting min.

Allows the device to be configured for a minimum tidal volume setting of 10ml or 5ml.

6.8 Overview of General Service Screens

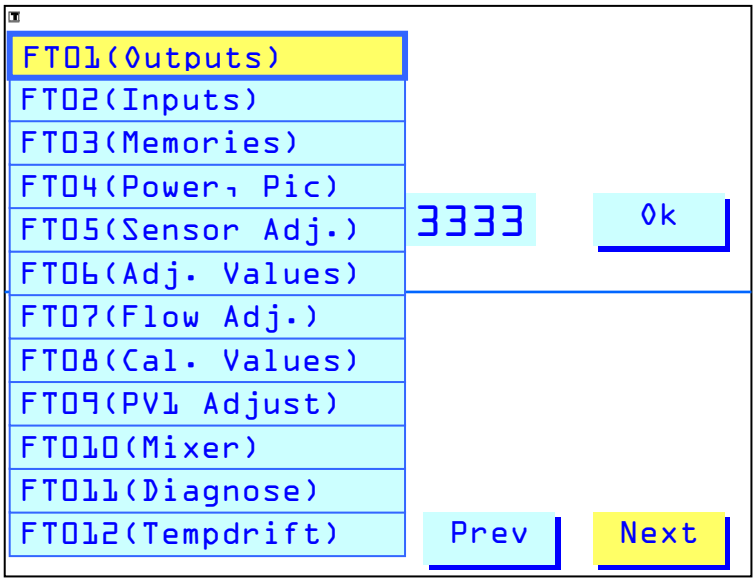


Figure 6-6

The individual fabrication screens may be accessed in a number of different ways. From the FabTest start screen select the field FT01 (Outputs) and a full pull down menu including all fabrication tests is available (Figure 6-6). Select the required FabTest from the menu and the device proceeds directly to that screen. Alternately you may proceed to the required screen by stepping through using the Next and Prev buttons.

6.9 Fabrication Test 1 - Outputs

Fabrication Test 1 - Outputs (Figure 6-7) allows the service technician to perform troubleshooting procedures and control a number of the components and circuits within the pneumatic and electronic systems.

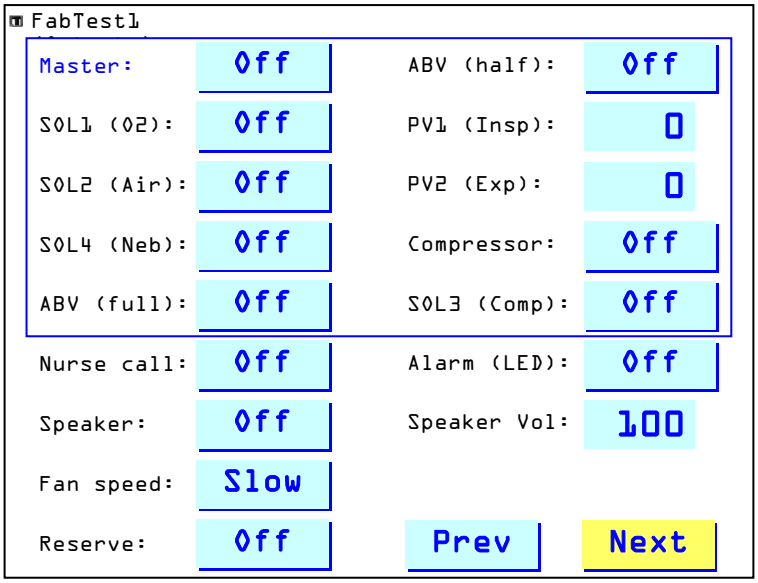


Figure 6-7

Each of the pneumatic valves, and associated electronic circuits within the system may be energized in order to confirm correct operation. To perform a test to a given pneumatic valve, the following procedure is followed:

Select Master and switch to On. Master must be switched on before any other pneumatic components may be enabled.

Note:

If using high pressure gases during troubleshooting with fabrication test 1 it should be noted that internal tank pressure will not be regulated. It is recommended that gases be regulated at source to approximately 1.5 bar (20 psi) to avoid opening the reservoir over-pressure valve.

Warning:

Using FabTest in an inappropriate way or by untrained personnel may seriously damage the ventilator.

With the master enabled, select the valve or combination of valves, as required to meet your testing goals. Proportional valves may be cycled through their full control range; PV1 (6022) 0-500, PV1 (2833) 0-1000, PV2 0-1000.

With the required components switched on the technician may observe the device for the response appropriate to each test to determine whether its operation is normal. On completion each item should be returned to the Off setting.

Some examples of how these functions might be used:

Checking PV1 operation; open SOL1 or SOL2 to charge the reservoir with gas, cycle PV1 through its control range; observe flow from the too patient port.

Checking SOL1 or SOL2 operation; open either SOL1 or SOL2 (whichever required), open SOL 4; observe flow from the nebulizer port.

These are just two examples, but by using these individual controls, or by combinations thereof, all of the device's pneumatic components may be tested for function.

In the same way the lower section of this fabrication test screen allows the technician to test a number of electrical circuits within the device. Once again navigate to the appropriate item, switch On or as appropriate, and observe for the required response.

Some examples of how these functions may be used:

Checking Nurse Call operation; attach a nurse's call test box to the nurse call RJ12 connector on the rear panel and connect a multi-meter or continuity tester. Switch nurse call Off/On and observe the test equipment for the required response.

Checking Back Up Alarm Operation; select Speaker On, select Speaker Vol and adjust below 12%, after a short period back up alarm is audible.

The following are the major components and circuits that may be tested:

Master	Pneumatic Master Circuit
SOL1 (O_2)	Oxygen Supply Solenoid (Sol 1)
SOL2 (Air)	Air Supply Solenoid (Sol 2)
SOL4 (Neb	Nebulizer Solenoid (Sol 4)
ABV (Full)	Safety Valve Solenoid
ABV (Half)	Safety Valve Solenoid
PV1 (Insp)	Inspiratory Proportional Valve (PV1
PV2 (Exp)	Expiratory Proportional Valve (PV2)
Compressor	Internal Backup Compressor (if installed)
SOL3 (Comp)	Compressor Unloading Solenoid (Sol 3)
Nurse Call	Nurses Call Relay Verification
Speaker	Main Alarm Speaker
Speaker Vol	Main Alarm Volume (0-100%)
Alarm LED	Front Panel Alarm LED
Fan Speed	Internal Cooling Fan (fast/slow)

6.10 Fabrication Test 2 - Inputs

Fabrication test 2 - Inputs (Figure 6-8) allows the service technician to observe the 16 channels of measured data used as inputs to the microprocessors AD converter. This measured data is for reference only. The status of ADC1 and ADC2 may be used for troubleshooting. See the FabTest 2 section of the Troubleshooting of Service Screens table (Section 6.21). This screen also allows a functional check to be performed on the user control panel keys.

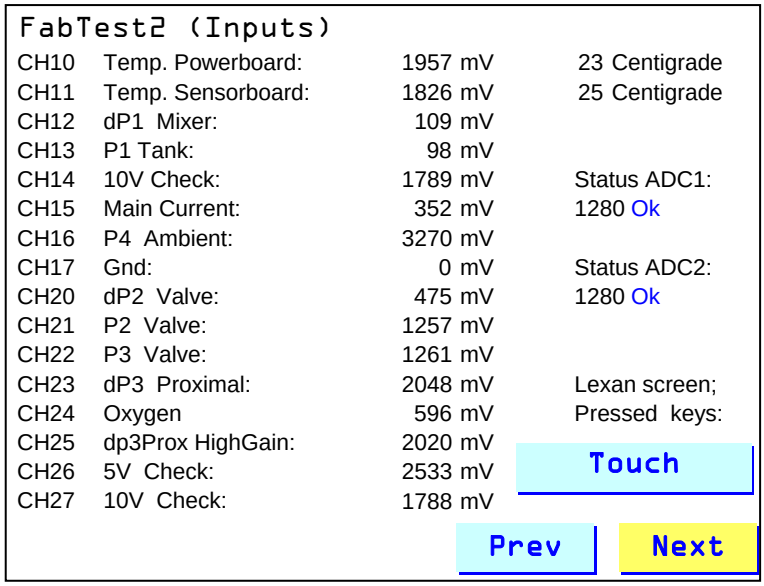

FabTest2 (Inputs)
CH10 Temp. Powerboard: 1957 mV 23 Centigrade
CH11 Temp. Sensorboard: 1826 mV 25 Centigrade
CH12 dP1 Mixer: 109 mV
CH13 P1 Tank: 98 mV
CH14 10V Check: 1789 mV Status ADC1:
CH15 Main Current: 352 mV 1280 Ok
CH16 P4 Ambient: 3270 mV
CH17 Gnd: 0 mV Status ADC2:
CH20 dP2 Valve: 475 mV 1280 Ok
CH21 P2 Valve: 1257 mV
CH22 P3 Valve: 1261 mV
CH23 dP3 Proximal: 2048 mV Lexan screen;
CH24 Oxygen 596 mV Pressed keys:
CH25 dp3Prox HighGain: 2020 mV
CH26 5V Check: 2533 mV
CH27 10V Check: 1788 mV
Touch
Prev
Next

Figure 6-8

The information included below lists and provides some additional detail of the individual A/D converter signals:

CH10	Temp Power board	Internal temperature at the Power board
CH11	Temp Sensor board	Internal temperature at the Sensor board
CH12	dP1 Mixer	Blender flow sensor FS1/dP1
CH13	P1 Tank	Reservoir pressure P1
CH14	+10V Check	10VDC supply monitor
CH15	Main Current	Main system current
CH16	Charge Current	Battery charging current
CH17	Gnd	Ground
CH20	dP2 Valve	Inspiratory flow sensor FS2/dP2
CH21	P2 Valve	Inspiratory pressure sensor P2
CH22	P3 Proximal	Proximal pressure sensor P3
CH23	dP3 Proximal	Proximal flow sensor FS3/dP3
CH24	Oxygen	Internal oxygen sensor
CH25	dP3 Prox HighGain	Proximal flow sensor high gain
CH26	+5V Check	5VDC supply monitor
CH27	+10V Check	10VDC supply monitor

Using FabTest2 the operation of each of the front panel keys may be verified. This is performed by pressing each of the keys and monitoring the pressed keys field on screen for the appropriate response.

The Touch Screen is also calibrated from this screen for units equipped with Touch Screen technology. Select Touch and then Cal Touch and follow the prompts to calibrate.

6.11 Fabrication Test 3 – Peripheral Memories

Fabrication test 3 – Peripheral Memories (Figure 6-9) allows the service technician to perform a checksum test on peripheral memory locations and verify installed hardware and software versions.

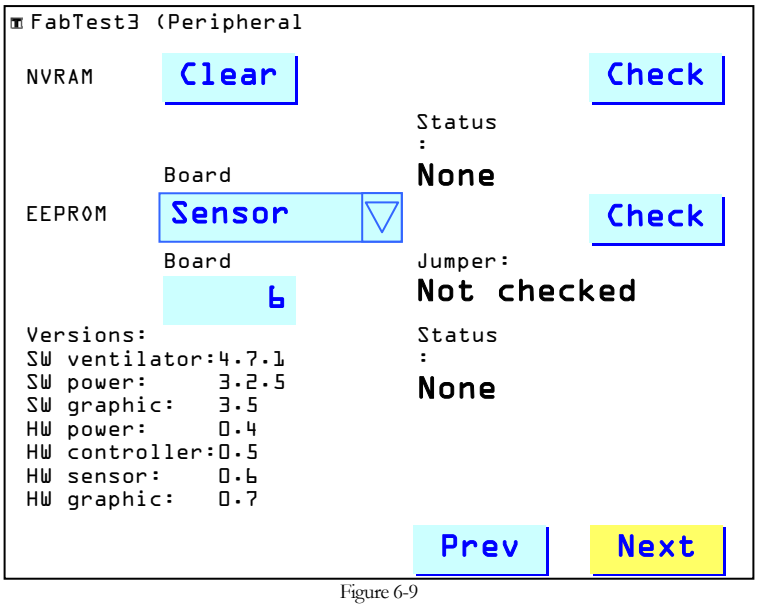


Figure 6-9

6.11.1 NVRAM Clear

Using this function clears all the stored information in NVRAM. Clearing NVRAM is recommended only after all other troubleshooting attempts fail. Clearing NVRAM requires the ventilator to be completely re-configured and re-calibrated. If NVRAM must be cleared see the Rebuilding NVRAM instructions in Section 6.22.

6.11.2 NVRAM Check

Using this function performs a full checksum pattern test of the NVRAM device and reports the pass/fail status.

6.11.3 EEPROM Board

This function reveals a pull down menu allowing the engineer to select which board is available for test. The technician may select between Sensor board, Power board and Controller (Motherboard) PCB.

6.11.4 Check EEPROM

Once the appropriate board has been selected (as described above) this function is used to perform a full checksum pattern test of its EEPROM devices. Device performs the test and reports a pass/fail status.

6.11.5 Board Version

This function allows the revision of the selected PCB to be determined without need for physical inspection.

6.11.6 Jumpers

This function allows the engineer to identify whether the selected PCB has any jumpers present without the need for physical inspection.

6.11.7 Versions

Allows the revisions for system, power and software versions to be determined; along with hardware revisions for the Graphic Board, Sensor board, Power board, and Controller (Motherboard) PCB, without the need for physical inspection.

6.12 Fabrication Test 4 - Power Controller

Fabrication Test 4 – Power Controller (Figure 6-10) allows the service technician to view data and values pertaining to the Power board, power processor and related areas:

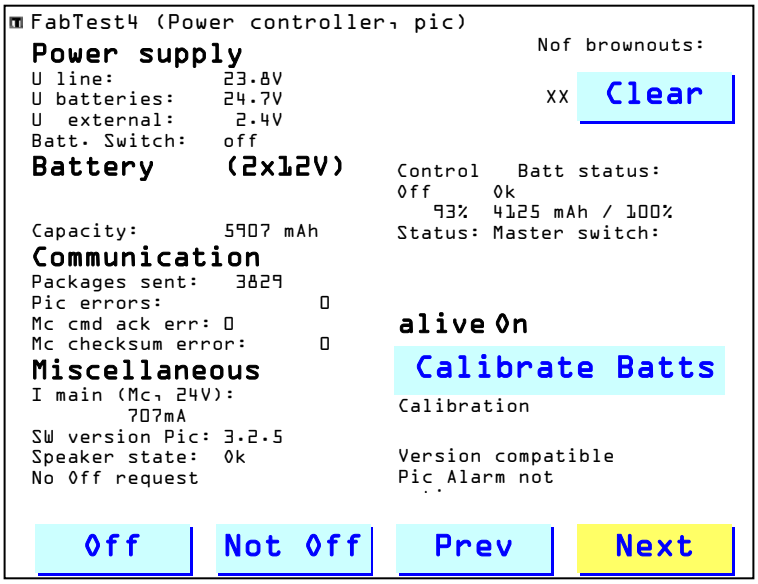


Figure 6-10

6.12.1 Power Supply

This area of screen 4 permits the service engineer to review the current power supply status. Measured values are available for the following:

U line – power supply voltage output derived from line voltage

U batteries – internal battery voltage

U external – external DC supply voltage

Additionally in this area of the screen the active power source status is verified. The following values are displayed at any time:

Line – AC power in use

Accu – internal battery in use

External – external DC supply in use

6.12.2 Battery (2 x 12v)

This area of the screen permits the service engineer to view information pertaining to battery condition and charging status. The values available in this area are as follows:

Battery Switch – Provides an indication of the status of the 2 battery circuits

Capacity – Current battery capacity, as a value (mAh) and as a percentage of maximum capacity. The left hand figure (a) represents current mAh measurement from the internal battery. The right hand figure (b) represents the maximum capacity available on the battery at last calibration cycle. The middle figure denotes the current capacity as % (a/b).

Control – Indicates whether battery charging is active. On denotes battery being charged, Off denotes no charging.

Batt status – Indicates the battery condition. OK denotes battery OK and available for use or charging. OFFLINE denotes battery which is damaged, disconnected or in a severely depleted condition.

Following is a brief table (Table 6-1) illustrating how different combinations of values from the above parameters may be used to define the current condition of internal batteries and associated circuitry:

Switch	Control	Status	Actual State
In-Line	Off	OK	1. Internal battery in use
Off	Off	OK	1. Internal battery fully charged
Split	On	OK	1. Internal battery on charge
Off	Off	Damaged	1. Internal battery voltage <10VDC. 2. Internal batteries incorrectly connected. 3. Battery charging circuit damaged.
Off	Off	Offline	1. Internal batteries not connected. 2. Internal batteries incorrectly connected. 3. Internal battery shorted 4. Replace Power board
Off	Off	Shorted	1. Internal batteries incorrectly connected. 2. Battery charging circuit damaged.

Table 6-1

6.12.3 Battery Calibration

The battery calibration function allows the service technician to perform a calibration of the internal batteries. This calibration procedure updates available capacity figure shown on the farthest right position in the capacity section of fabrication screen 4. The calibration runs automatically but does require operator action at certain points during the procedure.

To perform the calibration, select Calibrate Batts. With the selection made the device first charges the internal batteries fully. With the internal batteries charged the device alarms to highlight this fact and to prompt the operator to disconnect the AC power cord. On confirmation that AC mains is disconnected the device starts the internal compressor (if available), opens Sol 4, and runs a discharge cycle (note if internal compressor is not available this stage takes a considerable length of time). As the internal battery reaches the point of being flat the device alarms once again to highlight this fact and to prompt the operator to reconnect the AC power cord. Again on confirmation the device recharges the internal batteries fully. On completion the message Calibration Stopped is displayed and the capacity figure is updated.

6.12.4 Communications

This area of the screen permits the service engineer to view information pertaining to communications between the main system processor (Mc) and the power interface controller (Pic). The information available in these areas is as follows:

Packages Sent – Incremental number denoting the number of data packages exchanged between the power processor (PIC) containing power status information.

Pic Errors – Incremental number denoting the number of communication errors detected by the power processor (PIC).

Mc cmd ack err – Incremental number denoting the number package acknowledgement errors detected by the main microprocessor. PIC did not send an acknowledgement for a package sent by main processor.

Mc checksum err – Incremental number denoting the number of checksum errors detected by the main processor. Main processor has received a package with a bad checksum.

Status – Indicates the status of communications between the Pic and the Mc.

Master Switch – Indicates the condition of the pneumatic master control switch.

6.12.5 Miscellaneous

This area of the screen permits the service engineer to review miscellaneous information pertaining to the current condition of the Power control system. The information available in this area is as follows:

I main (Mc, 24v – Indicates the main system current draw measured at the Mc.

SW version Pic – Displays the current SW revision for the Pic.

Off request – Indicates whether there are pending off requests.

6.13 Fabrication Test 5 – Sensor Adjust

Fabrication Test 5 – Sensor Adjust (Figure 6-11) allows the service technician to perform a zeroing operation on all of the device's pressure transducers. Additionally the screen allows a calibration of purge flow offsets.

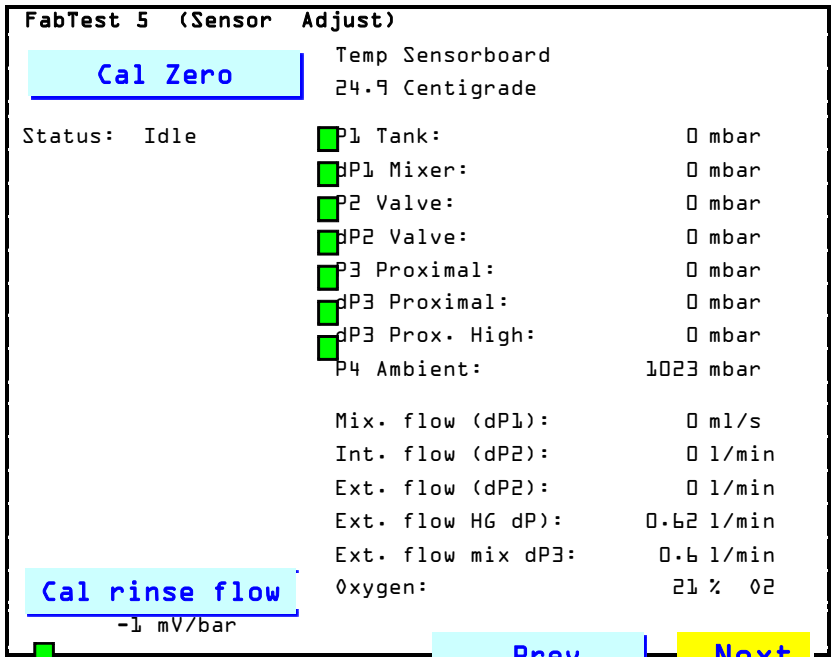


Figure 6-11

The sensor zero adjustment procedure or parts thereof, are required upon replacement of either the Sensor board or the Power board. In addition it is recommended these procedures are performed prior to performing any of the internal (during fabrication test) calibration procedures in order to eliminate any offsets. The sensor zero adjustment may be performed at any time troubleshooting suggests it is necessary.

Remove all pressure from the device prior to performing the zero procedure., If available, select Empty Tank which opens Sol 4 and vents all system pressure to atmosphere (on newer versions of software this is not necessary.) Ensure all tubing, including proximal sensor tubing, is removed from the device.

Select Cal Zero. The calibration runs automatically as each sensor is zeroed. For older versions of software a pull down menu appears to allow each sensor to be selected. Select the appropriate sensor and select Zero in order to perform the operation for the selected sensor. The device reports a pass or fail status. Repeat the processor for each sensor. The sensors available for zero adjustment in this way are; P1 Tank, dP1 Mixer, P2 Valve, dP2 valve, P3 Proximal, dP3 Proximal, dP3 Prox High Gain and Oxygen Sensor.

Cal rinse flow allows the device to quantify the amount of offset of dP3 (proximal flow) which may be caused by the effects of proximal purge flow. The slightest difference between the purge flows passing through the sensing lines and channels causes an offset on dP3. Reservoir pressure affects the amount of purge flow which is produced therefore as the reservoir pressure varies; the dP3 offset will also vary. Rinse flow calibration quantifies the affects at a range of pressures.

Prior to performing a rinse flow calibration it is recommended that all of the transducers are zeroed as a number of them are used during the procedure. Connect high pressure air with a pressure of at least

2 bar (29 psi) available. Remove the proximal flow sensor tubing from the ventilator. Select Cal rinse flow to commence calibration. The device operates the blending system to pressurize the reservoir to approximately 1500 mbar. With the reservoir charged the device allows the pressure to decay naturally through the purge flow and oxygen restrictors. The device checks dP3 offset between certain ranges of reservoir pressure down through to zero. Values are stored in NVRAM and an average result is displayed.

6.14 Fabrication Test 6 - Sensor Adjust Values

Fabrication Test 6 - Sensor Adjust (Figure 6-12) allows the service technician to review gain and offset data for all of the devices internal transducers. This information is for reference use only and not typically used in the field.

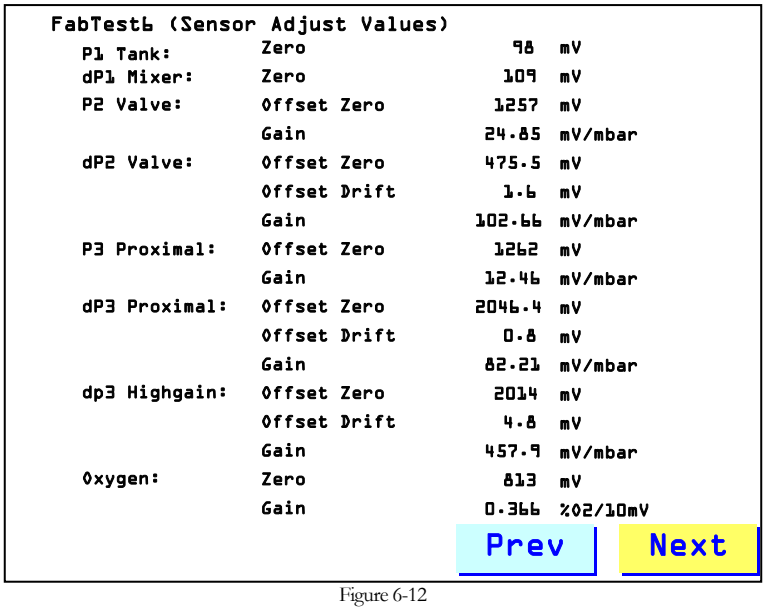

FabTest6 (Sensor Adjust Values)
P1 Tank: Zero 98 mV
dP1 Mixer: Zero 109 mV
P2 Valve: Offset Zero 1257 mV
Gain 24.85 mV/mbar
dP2 Valve: Offset Zero 475.5 mV
Offset Drift 1.6 mV
Gain 102.66 mV/mbar
P3 Proximal: Offset Zero 1262 mV
Gain 12.46 mV/mbar
dP3 Proximal: Offset Zero 2046.4 mV
Offset Drift 0.8 mV
Gain 82.21 mV/mbar
dp3 Highgain: Offset Zero 2014 mV
Offset Drift 4.8 mV
Gain 457.9 mV/mbar
Oxygen: Zero 813 mV
Gain 0.366 %O2/10mV
Prev
Next

Figure 6-12

The calibration data which are available on fabrication test 6 are as follows:

P1 Tank	Internal Tank Pressure
dP1 Mixer	Blender Flow Transducer
P2 Valve	Internal Pressure Transducer
dP2 Valve	Internal Flow Transducer
P3 Proximal	Proximal Pressure Transducer
dP3 Proximal	Proximal Flow Transducer
dP3 Highgain	High gain channel for proximal flow transducer
Oxygen	O_2 Measurement Cell

6.15 Fabrication Test 7 – Flow Sensor Adjust

Fabrication Test 7 – Flow Sensor Adjust (Figure 6-13) allows the service technician to perform a detailed calibration of the device's two internal flow measurement devices, FS1/dP1 blender flow sensor and FS2/dP2 internal flow sensor.

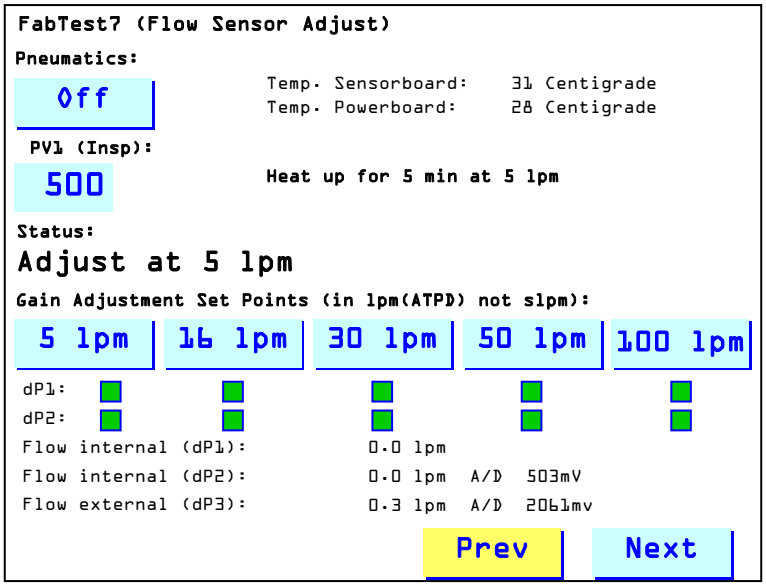


Figure 6-13

The flow sensor calibration procedure, or parts thereof, may be required upon replacement of the Blender Module, blender flow sensor (FS1/dP1), Front Interface Block, internal flow sensor (FS2/dP2), Sensor Board, Sensor Block 2, or the Motherboard. In addition the flow sensor calibration procedure may be performed at any time as troubleshooting suggests that it is necessary.

To perform this operation a calibrated flow analyzer is required. eVent Medical recommends the use of the TSI Certifier Plus flow analyzer or equivalent measurement device. Please ensure that any instrument used carries a valid calibration certificate. Test devices should be configured to measure Flow – Air with ATP (atmospheric temperature & pressure) correction. The test equipment set up is demonstrated in Figure 6-14 below.

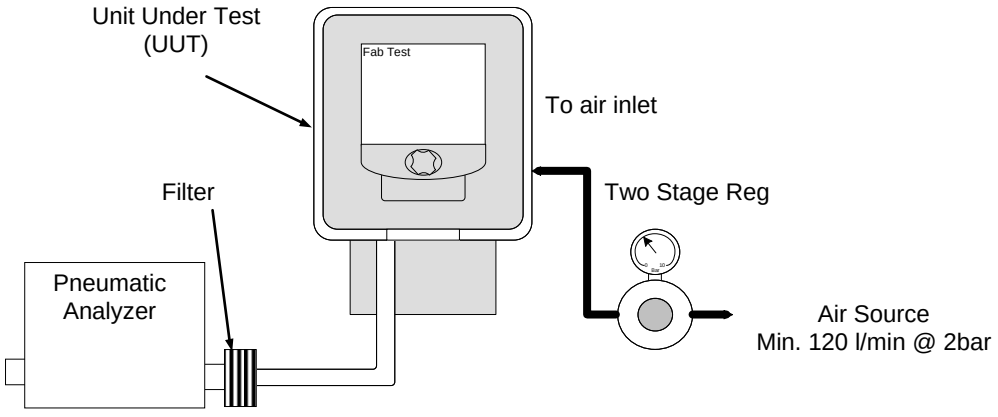


Figure 6-14

Prior to proceeding with FabTest 7 please ensure the ventilator has warmed up for at least ten minutes and the differential pressure sensors associated with internal flow measurements (dP1/dP2) have been zeroed. This is done via FabTest 5 as described previously.

Connect an adjustable high pressure Air source to the device's air inlet with its output initially set to its minimum. Attach a pneumatic analyzer to the To Patient connector of the ventilator using a short length of 22mm smooth bore tubing.

Select and switch On the Pneumatics. This operation enables the pneumatics master switch and opens the air blender valve. For optimal calibration results it is recommended that PV1 is not adjusted from its initial setting (PWM 250 for Type 6022, PWM 500 for Type 2833).

Increase the supply pressure until a flow of 5 l/min ± 0.05 is observed on the flow measurement device, allow the device to run with this flow for a period of not less than 5 minutes in order to permit PV1 to warm up.

On completion of this 5 minute period re-adjust flow if necessary, then with 5.0 l/min flow present select the gain adjustment set point for 5 l/min. The device performs a self-calibration and confirms when 5 l/min point has completed successfully.

With 5 l/min calibration complete, increase the supply pressure until a flow of 16 l/min ± 0.2 is observed on the flow measurement device.

With 16 l/min flow present select the gain adjustment set point for 16 l/min. The device performs a self-calibration and confirms when 16 l/min point has completed successfully.

With 16 l/min calibration complete, increase the supply pressure until a flow of 30 l/min ± 0.3 is observed on the flow measurement device.

With 30 l/min flow present select the gain adjustment set point for 30 l/min. The device performs a self-calibration and confirms when 30 l/min point has completed successfully.

With 30 l/min calibration complete, increase the supply pressure once more until a flow of 50 l/min ± 0.5 is observed on the flow measurement device.

With 50 l/min flow present select the gain adjustment set point for 50 l/min. The device performs a self-calibration and confirms when 50 l/min point has completed successfully.

With 50 l/min calibration complete, increase supply pressure once more until a flow of 100 l/min ± 1.0 is observed on the flow measurement device.

With 100 l/min flow present select the gain adjustment set point for 100 l/min. The device performs a self-calibration and confirms when 100 l/min point has completed successfully. Calibration is now complete.

Disconnect the pneumatic analyzer from the To Patient connector and adjust the gas pressure source back down to zero. Select and switch off the pneumatics.

For reference purposes at the bottom of this screen a measurement of blender flow (measured at FS1/dP1), internal flow (measured at FS2/dP2), and external proximal flow (measured at FS3/dP3 if connected) is provided.

On successful completion of the calibration procedure the boxes adjacent to dP1 and dP2 and beneath the flow calibration points are filled green, in the event that calibration data is corrupt or not present the boxes are filled magenta.

Note:

The calibration can be stopped at any point. This means if there is no high flow source available it is possible to only calibrate lower flow settings e.g. the 5l/min and the 16l/min point.

6.16 Fabrication Test 8 – Calibration Values

Fabrication Test 8 – Calibration Values (Figure 6-15) allows the service technician to review the calibration data for the device's internal flow transducers and oxygen sensor. This information is for reference use only and not typically used in the field.

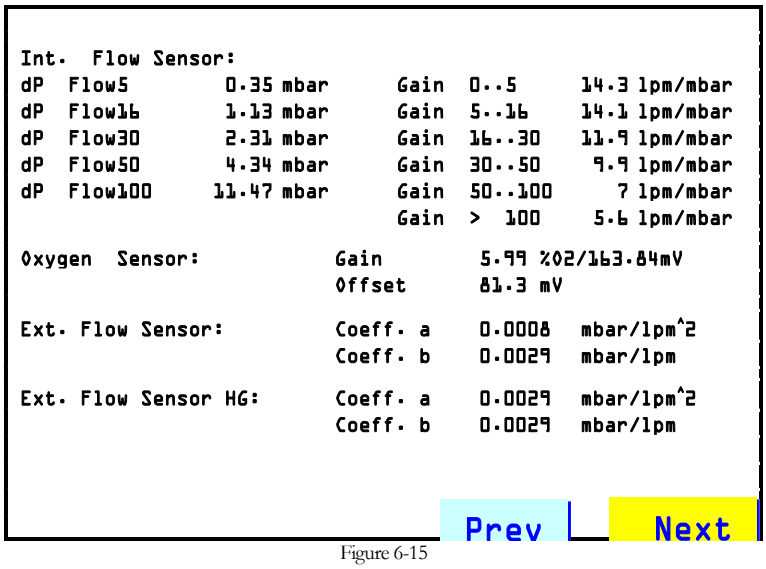

Int. Flow Sensor:
dP Flow5 0.35 mbar Gain 0..5 14.3 lpm/mbar
dP Flow16 1.13 mbar Gain 5..16 14.1 lpm/mbar
dP Flow30 2.31 mbar Gain 16..30 11.9 lpm/mbar
dP Flow50 4.34 mbar Gain 30..50 9.9 lpm/mbar
dP Flow100 11.47 mbar Gain 50..100 7 lpm/mbar
Gain > 100 5.6 lpm/mbar
Oxygen Sensor: Gain 5.99 %02/163.84mV
Offset 81.3 mV
Ext. Flow Sensor: Coeff. a 0.0008 mbar/lpm^2
Coeff. b 0.0029 mbar/lpm
Ext. Flow Sensor HG: Coeff. a 0.0029 mbar/lpm^2
Coeff. b 0.0029 mbar/lpm
Prev
Next

Figure 6-15

Internal Flow Sensor – This function permits the service engineer to observe the differential pressure and associated gain for each of the flows defined during calibration (5, 16, 30, 50, 100 l/min).

O_2 Sensor – This function permits the service engineer to observe the gain and offset values for the O_2 measurement cell as determined during the O_2 sensor calibration procedure.

Ext Flow Sensor – This function permits the service engineer to observe gain values for the proximal flow sensor resulting from its calibration relative to the delivery transducer.

6.17 Fabrication Test 9 - PV1 Adjust

Fabrication Test 9 – PV1 Adjust (Figure 6-16) allows the service technician to perform a calibration of the devices inspiratory proportional valve (PV1).

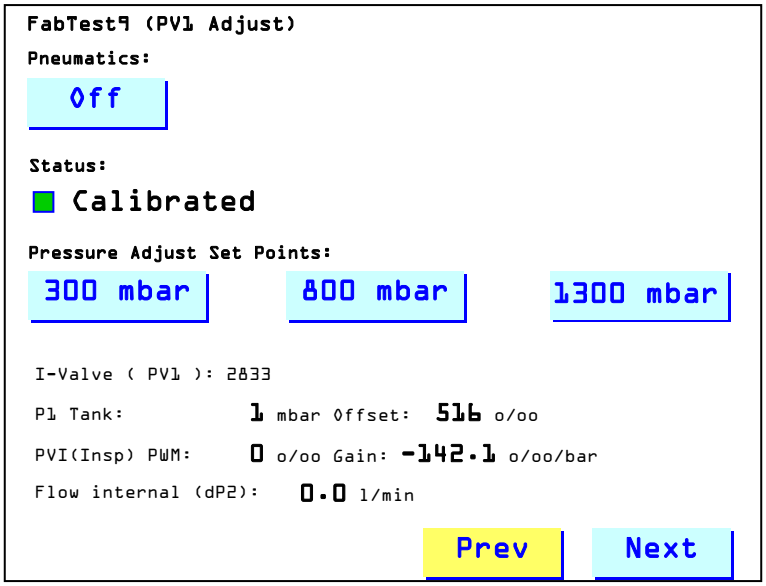


Figure 6-16

The inspiratory proportional valve calibration procedure may be required upon replacement of the inspiratory valve, Power Board, or the Motherboard. In addition the proportional valve calibration procedure may be performed at any time as troubleshooting suggests that it is necessary.

To perform this operation a high pressure air supply with adjustable pressure regulator is required. The test equipment set up is demonstrated in Figure 6-17.

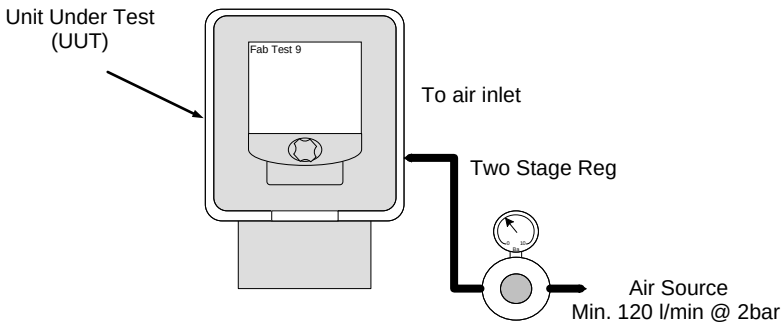


Figure 6-17

With the output set all the way off, attach an adjustable high-pressure air source to the ventilator.

Select and switch On the Pneumatics. This operation enables the pneumatics and opens the blender valves. PV1 also opens slightly to allow a small amount of flow to pass through.

Adjust the output of the high-pressure air source as necessary until a pressure of 300mbar ± 5 mbar is observed at P1 Tank on screen. With PV1 opened some flow is evident from the patient port.

Select the pressure adjust set point for 300mbar. Upon selection the device goes through a 200 second warming cycle in order to allow the valve to reach approximate operational temperature.

Note:

During this warming period the set tank pressure will deviate from the 300 mbar pressure which was originally set. The tank pressure must not be re-adjusted once the warm up cycle has commenced.

On completion of the warming cycle the PV1 is adjusted in to characterize the PWM required for a flow of 10 l/min at the internal flow sensor FS1. Proceed only when the device confirms successful calibration at this level.

Adjust the output of the high-pressure air source as necessary until a pressure of 800 mbar ± 10mbar is observed at P1 Tank on screen, once again some flow is evident from the To Patient port during adjustment.

Select the pressure adjust set point for 800mbar. Observe the PV1 PWM value is adjusted until a flow of 10 l/min is detected by the internal flow sensor. Proceed only when the device confirms successful calibration at this level.

Adjust the output of the high-pressure air source as necessary until a pressure of 1300 mbar ± 10mbar is observed at P1 Tank on screen, again some flow is evident from the To Patient port during adjustment.

Select the pressure adjust set point for 1300mbar. Observe the PV1 PWM value is adjusted until a flow of 10 l/min is detected by the internal flow sensor.

On completion the device displays pass/fail status. Switch off the pneumatics and reduce the output of the high pressure air source to 0.

6.18 Fabrication Test 10 - Mixer

Fabrication Test 10 - Mixer (Figure 6-18) allows the service technician to evaluate the function of the Internal blending system of the Inspiration ventilator. This information is for reference use only and not typically used in the field.

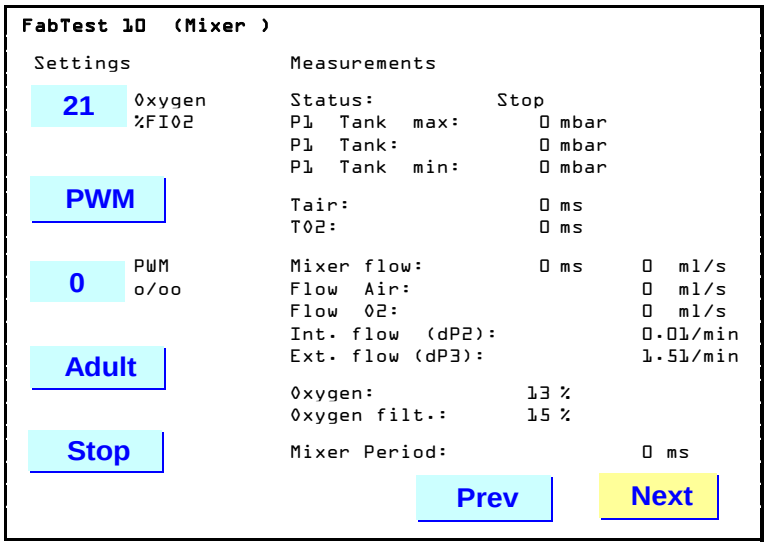


Figure 6-18

The following settings may be defined, the combination of which will allow any possible blender scenario to be simulated.

Oxygen % FIO_2 - Oxygen percentage delivered.

PWM - Determines the level to which PV1 is opened on each cycle.

Adult - This pull down menu allows settings for Adult (ADU), and Infant (INF) to be selected in order to determine the maximum tank pressure.

Stop – Allows ventilation to be commenced and stopped.

With the settings defined and in use the measurements area allows the following values to be monitored:

Status – Start/Stop according to whether ventilation is active.

P1 Tank – Current system tank pressure

P1 Tank Max – Maximum system tank pressure

P1 Tank Min – Minimum system tank pressure

TAir – Activation time for Air supply valve SV2

TO_2 – Activation time for O_2 supply valve SV1

Blender Flow – Flow measured at FS1/dP1

Flow Air – Flow from SV2 as measured at FS1/dP2

Flow O_2 – Flow from SV1 as measured at FS1/dP2

Oxygen – O_2% as measured at transducer

Oxygen filt – O_2% filtered signal

6.19 Fabrication Test 11 - Diagnose

Fabrication Test 11 - Diagnose (Figure 6-19) allows the service technician to view cumulative and diagnostic data. The data available for this screen is as follows:

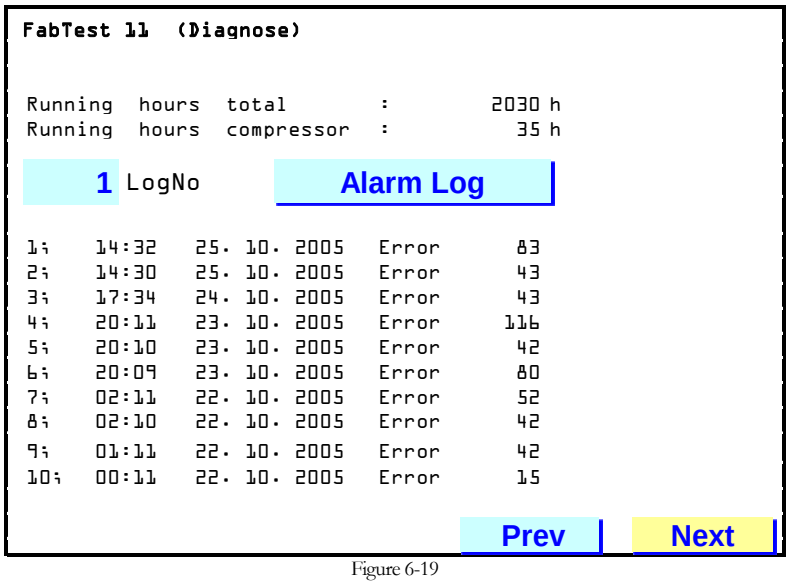


Figure 6-19

Running hours Total – This function allows the service engineer to determine the total elapsed running hours of the Inspiration system. Total running hours should be

consulted when determining requirements for preventive maintenance and should be recorded on the service report whenever work is performed.

Running Hours Comp – This function allows the service engineer to determine the total running hours of the integral compressor system. Compressor hours should be recorded on the service report whenever work is performed.

Alarm Log – Selecting the Alarm Log function will permit the service engineer to scroll through the ventilators error log. The first ten alarms are displayed and additional alarms are displayed by selecting the LogNo button and turning the knob to increment the log page. This log will store up to 500 events including technical errors and, high priority and medium priority alarms. Technical errors are highlighted with an asterisk (*) following the alarm number. By turning the rotary control knob the engineer may view the entire contents of the log. Errors will appear in the following format:

A: BB:BB CC.CC.CCCC ERROR XX

A: = Position within the event log (where 1 is the most recent event)
B: = Time the event occurred in 24 hour format
C: = Date on which the event occurred
XX = Two digit number representing the type of even which occurred

For a detailed description of each error and associated troubleshooting data please refer to the DIAGNOSTIC ERROR CODES and ALARM MESSAGES section of this technical manual.

Settings Log – The Settings Log is accessed by Selecting the Alarm Log button. Repeated selections of the button toggles between the Alarm Log and Settings Log. Selecting the Settings Log function permits the service engineer to scroll through the ventilators settings log. The first ten settings changes are displayed and additional changes are displayed by selecting the LogNo button and turning the knob to increment the log page. This log stores up to 1573 ventilator settings changes. By turning the rotary control knob the engineer may view the entire contents of the log. Settings appear in the following format:

A: BB:BB CC.CC.CCCC XXX YYY ZZZ

A: = Position within the event log (where 1 is the most recent event)
B: = Time the event occurred in 24 hour format
C: = Date on which the event occurred
XXX = Three digit number representing the type of settings change which occurred
YYY = Value before change
ZZZ = Value after change

Contact eVent Medical, Inc. at service@event-medical.com for assistance with settings change codes.

6.20 Fabrication Test 12 – Adjust Temp drift dP2, dP3

Fabrication Test 12 - Adjust Temp drift dP2, dP3 (Figure 6-20) allows the service technician to perform a temperature drift compensation for the differential pressure transducers dP2 (Internal flow sensor) dP3 (proximal flow sensor) and dP3 HG (proximal flow sensor high gain).

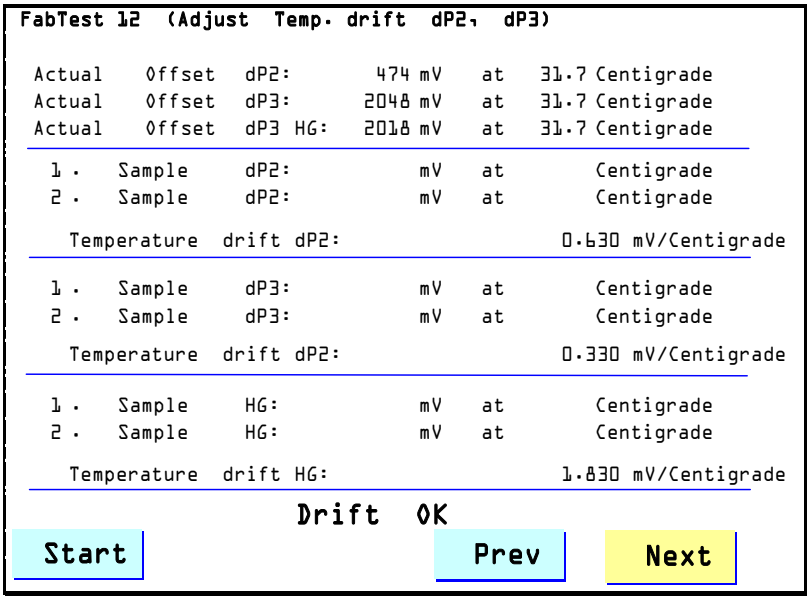

FabTest 12 (Adjust Temp. drift dP2, dP3)
Actual Offset dP2: 474 mV at 31.7 Centigrade
Actual Offset dP3: 2048 mV at 31.7 Centigrade
Actual Offset dP3 HG: 2018 mV at 31.7 Centigrade
1. Sample dP2: mV at Centigrade
2. Sample dP2: mV at Centigrade
Temperature drift dP2: 0.630 mV/Centigrade
1. Sample dP3: mV at Centigrade
2. Sample dP3: mV at Centigrade
Temperature drift dP2: 0.330 mV/Centigrade
1. Sample HG: mV at Centigrade
2. Sample HG: mV at Centigrade
Temperature drift HG: 1.830 mV/Centigrade
Drift OK
Start
Prev
Next

Figure 6-20

Temperature drift compensation should be performed only when performance testing indicates that it may be necessary. Indications may be an unexplained flow baseline rise or fall during ventilator operation.

Note:

Observe the temperature display at the top of FabTest 12 screen. Drift calibration should only be started if temperature is between 20- 25 degrees Celsius. If temperature is above this level switch device off and unplug from AC mains, in order to allow cooling.

Temperature drift compensation is performed as follows:

Prior to commencing the temperature drift compensation remove side rails and mounting hardware from the device so the front housing is loosely fitted to device (LG only.)

Prior to commencing the temperature drift compensation remove the four screws that secure the front housing (LS only.)

Ensure that all patient tubing, proximal flow sensor, and inlet gases have been removed from the device. Select Start to commence the procedure.

The device prompts you to Connect Jumper. At this request remove the front panel or housing to a point where the Sensor board is accessible.

Install a jumper in the vacant position on the top/middle of the Sensor board (J1), and then place the front housing back in position.

Select Ok to confirm the jumper is in position, then Ok once more to confirm the front housing has been replaced.

A two point calibration is performed by the device. The device takes and stores an initial cold reading and then starts the internal compressor. The compressor is allowed to run for an extended period (approximately two hours) in order to elevate the device's internal temperature following which a second reading is taken and stored.

On completion the device prompts you to Remove Jumper. Remove the jumper by reversal of the installation and select Ok to acknowledge completion.

6.21 Troubleshooting of Service Screens

The device reports a pass or fail status on completion of each applicable calibration. In the event of a failure the device reports a specific error message indicating the nature of the problem. Definitions and possible steps for resolution are listed in the table below:

Error	*Diagnosis*	*Troubleshooting*
FabTest 1:		
Valve / Component does not cycle	Valve / Component does not cycle when selected	1. Ensure Master is on 2. Ensure that the communication with Power processor is alive (FabTest 4) 3. Ensure that that relevant output is on 4. Replace component relevant to the output. 5. Replace Power board 6. Replace Processor Board
FabTest 2:		
ADC 1: Error	Error On A to D Converter 1	1. Ensure all ribbon connectors are seated correctly. 2. Replace Sensor board. 3. Replace Power board. 4. Replace Processor Board
ADC 2: Error	Error On ADC 2	1. Ensure all ribbon connectors are seated correctly. Replace Sensor board 2. Replace Power board 3. Replace Processor Board
No response from pressed button	No machine response to pressing one or all Lexan button	1. Ensure that ribbon cable from lexan to controller is secure 2. Replace lexan screen 3. Replace Motherboard 4. Replace Processor Board
FabTest 3:		
NVRAM Check Sum Error	Bad checksum from non volatile memory	1. Ensure that the Processor Board is securely located 2. Clear NVRAM & repeat checksum 3. Replace Controller PCB

Error	*Diagnosis*	*Troubleshooting*
NVRAM Check Sum Error after Power Up	Bad checksum from non volatile memory	1. Replace snap heat battery of NVRAM
Sensor board Checksum Error	Bad checksum from Sensor board	1. Ensure that all ribbon cables are securely located 2. Replace Sensor board
Motherboard Checksum Error	Bad checksum from Motherboard	1. Ensure that all ribbon cables are securely located 2. Replace Motherboard
Power board Checksum Error	Bad checksum from Power board	1. Ensure that all ribbon cables are securely located 2. Replace Motherboard
FabTest 4:		
U line low	Power Supply output low	1. Ensure mains supply connected 2. Ensure inlet fuses ok 3. Check internal wiring, AC inlet to power supply to Power board 4. Using DMM verify output from power supply. If bad replace power supply 5. Replace Power board
U Batteries low	Internal Battery output low	1. Ensure battery is charged sufficiently before proceeding 2. Replace internal batteries 3. Check DC power harness 4. Replace Power board
U External low	External DC output low	1. Ensure external DC Supply is switched on and harness connected 2. Check internal DC harness & connections to external supply connector. 3. Check fuses on the Power board. 4. Replace Power board
Speaker state not ok	Audio amplifier, speaker or supervision circuitry damaged	1. Replace Power board
Batt. status damaged	Batteries flat	1. Replace Internal batteries 2. Replace Power board
Communication errors > 0	Non secure communication between Power Processor and Main Processor	1. Replace Motherboard ribbon cable 2. Replace Power board 3. Replace Processor Board

FabTest 5:		
Zero Error (P1, dP1)	Unable to zero pressure transducer	1. Ensure that all pressure is removed from reservoir 2. Attempt re-zero once more 3. Replace Power board 4. Replace Sensor board
Zero Error (P2, dP2, P3, dP3)	Unable to zero pressure transducer	1. Ensure that all pressure is removed from system 2. Ensure that patient system & proximal flow sensor are not connected 3. Attempt re-zero once more 4. Replace Sensor board
Cal rinse flow error		
Error, Gas Supply	Unable to pressurize tank	1. Connect high pressure air
Error, Leak	Pressure in the tank dropped too fast	1. Make sure the check valve CV1 is not blocked or CV2 is not leaking backwards 2. Make sure the valves SOL4 , TOP and PV1 are not leaking 3. Replace tank module
Error, Cal	Unable to measure the influence of the rinse flow to the flow measurement	1. Make sure no proximal flow sensor is connected 2. Check the internal tightness of both proximal flow sensor lines 3. Sensor board: make sure that there is no leak between the block and the nipples of the pressure transducers 4. Replace CV3 and/or CV4 5. Replace Sensor board
***FabTest 6*:**		
No Relevant Errors	N/A	N/A
***FabTest 7*:**		
No flow	No flow measured on test flow meter	1. Ensure that tubing is securely connected with no leaks 2. Assure gas flow meter is operating properly 3. Check in Config 1 screen the selected model # of PV1 is correct 4. Verify electrical connections to PV1 5. Replace PV1 valve 6. Replace Power board

Gain Errors High/Low	Gain error during internal flow sensors calibration	1. Make sure only Air is used for calibration 2. Re-zero pressure transducers (FabTest 5) 3. Ensure that measured flow is within tolerance and gas standard is ATP (actual temperature and) 4. Replace internal flow sensor FS1 and /or FS2, depending on error 5. Replace Sensor board 6. If error is on dP1: replace Power board
FabTest 8:		
No Relevant Errors	N/A	N/A
FabTest 9:		
Error: Pressure High or Low	Tank pressure out of range (300 ±100 mbar)	1. Assure Tank pressure is adjusted to 300mbar
Error: Flow high	Flow at start of calibration too high (6022 > 4 l/min; 2833 > 30 l/min)	1. Ensure that supply to device is stable and holding at required level (may need to use better pressure regulator) 2. Replace PV1 valve
Error: Pressure dropped	Pressure drop out of range during calibration step	1. Ensure that supply to device is stable and holding at required level (may need to use better pressure regulator) 2. Re-zero pressure transducers (FabTest 5) 3. Replace PV1 valve
Error: Adjusting	Offset or gain value out of range	1. Ensure that supply to device is stable and holding at required level (may need to use better pressure regulator) 2. Replace PV1 valve
FabTest 10:		
No Relevant Errors	N/A	N/A
FabTest 11:		
No Relevant Errors	N/A	N/A
FabTest 12:		
Error: Offset dP2 Error: Offset dP3 Error: Offset dP3 High Gain	Offset value out of range	1. Ensure that all pressure is removed from reservoir and gas inlet hoses are disconnected 2. Re-zero pressure transducers in FabTest 5

Error: Temperature rise too low	Inadequate temperature rise during drift	1. Allow device to cool down (between 20-25C) then re-run. Ensuring the compressor or test fixture is installed and functional 2. Ensure the front housing is on and secured during the test
Error: Drift dP2 Error: Drift dP3 Error: Drift dP3 High Gain	Excessive drift	1. Allow device to cool down (between 20-25C)and then re-run 2. Replace Sensor board
Error: Writing EEPROM	EEPROM is still write protected	1. Install the jumper to allow programming of the EEPROM on the Sensor board (J1)

6.22 Rebuilding NVRAM

6.22.1 Perform a Manufacturing Configuration:

a. Enter the Manufacturing Config Entry: screen by holding in the Man Insp and Nebulizer keys while powering up the ventilator.

b. Enter 3333 in the Code field and select Ok to enter the Manufacturing Config 1 (Device Setup) screen.

c. Enter the correct value for the I-Valve (PV1): The inspiratory valve type can be identified by looking at the model number printed on the side of the PV1 solenoid.

d. Enter the correct value for the E-Valve (PV2: the exhalation valve type can be easily identified by the cap on top of the exhalation solenoid. Rev 6 has a blue plastic cap and all others (up to rev 5) have no cap and the spring is visible.

e. Enter the correct value for the Compressor: This refers to the ventilator's internal compressor. Select big (8009) if there is an internal compressor installed.

f. Select Next to advance to the Manufacturing Config 2 (Feature Setup) screen.

g. Configure the ventilator as follows:

Languages:	All languages
Smart Sigh:	On
RS232 Keepalive:	On
Enable Moist. 'None':	On
NCPAP / NIV:	On
VTV Volume Not Del. Alarm:	On

h. Enter 6002 (8991 for older software revisions) in the Code field and select Ok to enter the Manufacturing Config 3 (advanced Setup) screen.

i. Configure the ventilator as follows:

VTV:	On
Auto mode:	On
SPAP:	On
Patient Range:	All
Heliox (21%O2, 79%He):	On
Nebulizer interval:	On **Note:** Nebulizer interval is not approved for use in the United States and must be selected Off.
Rexp value:	On Note: Rexp value is not approved for use in the United States and must be selected Off.
Vt setting min.:	5ml / 10ml (depending on PV1 type) Note: 5ml Tidal volume has not approved for use in Japan and must be set to 10ml instead.

j. Switch the ventilator off.

6.22.2 Perform a User Configuration:

a. Enter the User Configuration screen by holding in the On/Off and Special keys while powering up the ventilator.

b. Enter 1998 in the Code field and select Config to enter the CONFIGURATION 1 screen.

c. Configure the ventilator as follows:

O2 sensor:	On
Compressor backup:	On
Philosophy:	Europe/US (Customer choice)
RS232 Protocol:	Inspiration/PB 7200 (Customer choice)
Alarm volume:	100%
Altitude above sea level:	(Set based on ventilator location**) Note: Must be adjusted to at least 1 ft.**

d. Select More to enter the CONFIGURATION 2 screen.

e. Configure the ventilator for the desired language and set the correct time and date.

f. Enter any desired number except 0 in the Service code field.

g. Select Exit.

h. Turn off the ventilator.

6.22.3 Perform a Check of the NVRAM:

a. Enter the Manufacturing Config Entry: screen by holding in the Man Insp and Special keys while powering up the ventilator.

b. Select FT01 (Outputs) under the FabTest Entry menu.

c. Select FT03 (Memories) from the dropdown list.

d. Select Check in the upper right of the screen.

e. The Status must read: Checksum Ok

6.22.4 Perform a Sensor Adjust:

a. Select Next to move to the FabTest 5 (Sensor Adjust) screen. Reference section 6.13.

b. Disconnect the high pressure air and oxygen if attached and remove the patient circuit including the proximal flow sensor tubing.

c. Select Empty Tank to de-pressurize the system (if applicable.)

d. Zero each of the pressure sensors by selecting them from the drop down menu and then selecting Zero for each one accept the Oxygen sensor.
Note: It is not necessary to zero the oxygen sensor.

6.22.5 Perform a Flow Sensor Adjust:

a. Select Next to move to the FabTest 7 (Flow Sensor Adjust) screen. Reference section 6.15.

b. Connect an adjustable high pressure Air source to the devices air inlet with its output initially set to its minimum.

c. Attach a calibrated flow measurement device to the To Patient connector of the ventilator using a short length of 22mm smooth bore tubing.

d. Select and switch on the Pneumatics.

e. Select PV1 (Insp) and adjust from its setting to the maximum.

f. Increase the supply pressure until a flow of 5 l/min ± 0.05 is observed on the flow measurement device. Allow the device to run with this flow for a period of not less than 5 minutes in order to permit PV1 to warm up.

g. After the 5 minute period re-adjust flow if necessary, then with 5 l/min flow present select the gain adjustment set point for 5 l/min.

h. Increase the supply pressure until a flow of 16 l/min flow is present and select the gain adjustment set point for 16 l/min.

i. Increase the supply pressure until a flow of 30 l/min flow is present and select the gain adjustment set point for 30 l/min.

j. Increase the supply pressure until a flow of 50 l/min flow is present and select the gain adjustment set point for 50 l/min.

k. Increase the supply pressure until a flow of 100 l/min flow is present and select the gain adjustment set point for 100 l/min. Calibration is now complete.

l. Disconnect the test flow meter from the To Patient connector and adjust the gas pressure source back down to zero.

m. Select and adjust PV1 to 0.

n. Select and switch off the pneumatics.

6.22.6 Perform a PV1 Adjust:

a. Select Next to move to the FabTest 9 (PV1 Adjust) screen. Reference section 6.17

b. Select and switch on the Pneumatics.

c. Ensure the P1 Tank display reads 0mbar ± 50mbar. If the reading is outside of this range select Nebulizer On to relieve the tank pressure. When pressure is observed to be within the acceptable range turn the Nebulizer Off and continue with the calibration.

d. Increase the supply pressure until a pressure of 300 mbar ± 5 mbar is observed at P1 Tank on screen.

e. Select the 300 mbar Pressure Adjust Set Point.

f. Increase the supply pressure until a pressure of 800 mbar ± 5 mbar is observed at P1 Tank on screen.

g. Select the 800 mbar Pressure Adjust Set Point.

h. Increase the supply pressure until a pressure of 1300 mbar ± 5 mbar is observed at P1 Tank on screen.

i. Select the 1300 mbar Pressure Adjust Set Point.

j. Switch off the pneumatics and reduce output of high-pressure air source to 0.

k. Switch the ventilator off.

Section

7

PERFORMANCE VERIFICATION

7.1 Introduction

This section of the Inspiration Series Ventilator Technical Manual is provided to allow the trained service technician to complete performance verification testing required periodically and post repair to ensure operation to the manufacturer's specifications.

Note:

The Inspiration Series Ventilator is manufactured with accurate pneumatic and electronic test equipment and in a controlled environment. The following test specifications were established with the test equipment specified in this section.

The procedures in this section do not apply to ventilator accessories. Refer to the user and technical manuals of the accessories. Malfunctioning accessories may affect some ventilator functions and may result in false test results.

7.2 When to Run Tests

The performance verification procedure and certain relevant FabTests (as defined in section 6 SERVICE MODE / FABTESTS of this manual), or parts thereof, should be run periodically or after a service has been performed as defined in Table 7-1 below:

			(FabTest)			Performance Tests				
Interval/Service Performed	**POST**	**Electrical Safety Tests**	**5**	**7**	**9**	**1**	**2**	**3**	**4**	**5**
Annually following annual preventive maintenance	X	X	X			X	X	X	X	X
Processor Board	X	X				X	X	X	X	X
Motherboard	X	X	X	X	X	X	X	X	X	X
Graphic Board	X	X				X	X	X	X	X
LCD Panel	X	X				X	X	X	X	X
Sensor board	X	X	X	X	X	X	X	X	X	X
Power board	X	X	X		X	X	X	X	X	X
Power Supply	X	X	X			X	X	X	X	X
Proportional Valve PV1	X	X	X	X	X	X	X	X	X	X
Flow Sensor SV1/SV2	X	X	X	X		X	X	X	X	X
Expiratory Valve PV2	X	X	X			X	X	X	X	X
Blender Valve SV1/SV2	X	X	X			X	X	X	X	X
SV3/Compressor	X	X								X
Oxygen Sensor	X	X								
Rotary Control Knob	X	X								
Inlet Filter	X	X								

Table 7-1

7.3 Test Equipment and Service Materials

Description	Manufacturer / Part No
Pneumatic Analyzer	TSI Certifier Plus or equivalent
Electrical Safety Tester	Biotek 601 Pro or equivalent
Adult Tubing System	Local supply
Pediatric Tubing System	Local Supply
Infant Tubing System	Local Supply
Proximal Flow Sensor, Adult	eVent Medical, F910203
Proximal Flow Sensor, Infant	eVent Medical, F910204
Exhalation Cover	eVent Medical, F710214
Exhalation Membrane	eVent Medical, F710213
Test Lung	Local Supply
High Pressure Air Supply with Adjustable Pressure Regulator	Local Supply (medical grade)
High Pressure Oxygen Source	Local Supply (medical grade)
Isopropyl Alcohol	Local Supply

7.4 Cleaning and Inspection

WARNING:

To prevent transmission of disease, use personnel protective equipment when handling any contaminated filters, HME's or other patient accessories.

CAUTION:

To prevent damage to ESD sensitive components, always follow ESD guidelines when servicing and handling components inside the ventilator.

NOTE

If you find any problems during the preliminary ventilator inspection, correct them before proceeding with the performance verification. Failure to correct such problems may affect the remainder of the performance verification procedure.

Clean and inspect the ventilator by the following means:

- Clean the ventilators exterior using appropriate germicidal or antibacterial agent. Clean all exterior surfaces including gas connections, water traps and the mains cord.
- Remove and inspect the ventilator's fan inlet filter, clean or replace it as is necessary.
- Verify that the air and oxygen fittings and water traps are securely attached to the ventilator. Inspect the inlet filters for excessive discoloration, replace as necessary.
- Open the ventilator chassis and inspect for cleanliness, as necessary clean its interior using an ESD safe vacuum cleaner.

- Visually inspect the ventilator's interior and exterior for any obvious problems such as missing or broken parts; loose assemblies, disconnected wires, connectors or tubes. Repair as necessary prior to performing the performance verification procedure.

7.5 Test Equipment Set Up

Prior to commencing the performance verification procedure any test equipment used should be examined. Check each device is in full working order and, as appropriate, they hold valid calibration certificates.

If using a pneumatic analyzer please ensure the device is allowed a minimum of 15 minutes warm up time prior to use. Only on completion of the warm up time should any self calibration (zero calibration, O_2 sensor calibration etc) be attempted.

7.6 Performance Testing

In order to ensure a systematic performance verification and logical fault diagnosis perform these tests in the order given. If you need to repeat a test, the current control settings are fully defined at the beginning of each individual test.

NOTE:

To locate the cause of any malfunction or test failure you should refer to the troubleshooting information provided at the rear of this section and more comprehensively in the Diagnostic Error Codes and Alarms section of this manual.

Follow these general guidelines when running the performance verification procedure:

- If you note a problem during the performance verification, verify that you have followed all procedures correctly, and that all required settings are correct, before attempting to perform any repairs on the device.
- When making changes to ventilator settings, be aware that because of the interrelationships between some settings, you may not always be able to make changes in the indicated sequence.
- For convenience any user configurable alarms should be set to maximum and minimum ranges available, this will reduce the occurrence of nuisance alarms during the performance verification.
- Use the alarm silence key as required during the performance verification procedure to mute any alarms should they occur.
- Except for the alarm silence key do not alter the control settings during these procedures unless specifically instructed to do so.
- Refer to the Service and Repair section of this manual for service and repair information, and the Parts List section for identification of repair parts. When repairs have been completed repeat the test in full.

NOTE:

The procedures described here within do not verify the performance of any accessories items (humidifiers, monitors, etc) which may be running with the ventilator system. Verify the performance of any such items using appropriate procedures within the applicable operation and service instructions.

7.7 Electrical Safety Testing

The electrical safety test is performed in order to verify that ground resistance and earth leakage current are within acceptable safe limits. This test is performed whenever the ventilator is opened for service, annually or more frequently should local regulations require it. Figure 7-1 below shows the basic set up for the test along with appropriate test points.

eVent Medical recommends the use of a Biotek 601 Pro or equivalent device for electrical safety testing on Inspiration series ventilators.

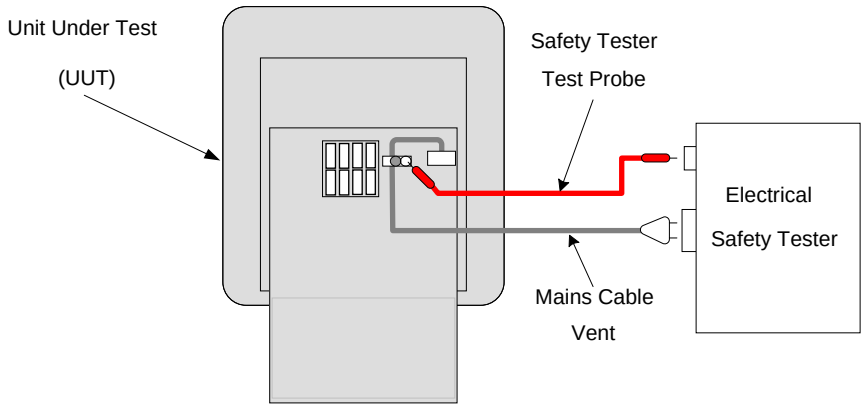


Figure 7-1

Perform the electrical safety test procedure as follows:

With the device switched off, plug the mains cable of unit under test (UUT) into the appropriate receptacle on the electrical safety tester.

Clip the ground test probe of the electrical safety tester to the retaining screw of the mains cable P-clamp on the rear panel of the UUT, as demonstrated in Figure 7-1.

Initiate a ground resistance test in the appropriate manner and observe the display on the electrical safety tester for the test result.

The ground resistance test value must be <0.2Ω.

Switch the UUT on and allow it to run and successfully complete its power on self test.

Initiate a leakage current check in both forward and reverse polarities.

The earth leakage current test value must be <300µA for both forward and reverse polarities.

Switch the UUT Off and disconnect it from the electrical safety tester.

7.8 Fabrication Tests

Per the detailed instructions in section 6 SERVICE MODE / FABTESTS section of this technical manual perform FabTest 5 in order to re-zero all pressure transducers.

7.9 Performance Verification Tests

7.9.1 Pneumatic Analyzer

Switch on the pneumatic analyzer and ensure that a warm up period of at least 15 minutes is allowed prior to proceeding.

Perform any required calibration procedures on the test device including any flow, pressure or oxygen sensor calibrations.

During the performance verification, measurements are taken from the pneumatic analyzer for volume, pressure, respiratory rate and oxygen. For convenience, and if possible, configure the analyzer so all these parameters appear on one screen.

To ensure the accuracy of volume measurements during the performance verification the pneumatic analyzer must be configured to measure in ATP (atmospheric temperature and pressure) mode. The gas type must be Air/O_2 and if available the inspiratory and expiratory trigger levels should be set to 1 l/min.

7.9.2 Unit Under Test (UUT) Configuration

Switch the device on in the Manufacturing Config/FabTest Entry screen by pressing and holding the Man Insp and Special keys during startup.. On completion of power on self test the start up screen is displayed. In the code entry field enter 3333 then select Ok to access the manufacturing configuration screens.

Manufacturing Config 1 (Device Setup) is displayed; select Next to proceed to Manufacturing Config 2 (Feature Setup). Make a note of all of the values selected on each of the 2 manufacturing configuration screens prior to proceeding, so the UUT may be returned to the same state after testing.

The performance verification requires the following settings:

Compressor: big (8009)

Smart Sigh: On

Enable Moist. None: On

If the UUT is an Infant only ventilator proceed to the Manufacturing Config 3 (Advanced Setup) screen by entering 6002 in the code entry field located on manufacturing screen 2 and selecting Ok. Note: for early software revisions enter 8991 in the code entry field. Change the Patient Range from Infant Only to All. Make sure to return the Patient Range to Infant Only when the performance verification testing is complete.

Adjust these settings as necessary then switch the UUT off.

Switch the device on in the user configuration mode by pressing and holding the Special and On/Off keys. On completion of power on self test the Standby screen is displayed. In the code entry field enter 1998 then select Config in order to access the CONFIGURATION 1 screen. Make a note of all of the values selected throughout the user configuration screens prior to proceeding, so the UUT may be returned to the same state after testing.

The performance verification requires the Prox flow sensor:, O2 sensor: and Compressor backup: all are set to On. Note: On later software revisions the Prox flow sensor selection may be found on the main Standby screen. Additionally it requires that Philosophy: is set to US. Adjust these settings as necessary then switch the UUT off.

7.9.3 Unit Under Test (UUT) Set-Up

Connect high pressure air and oxygen supplies to the UUT, supply outlet pressure should be adjusted to 4 bar ± 1 bar (45-72 PSI).

For the initial test set up connect a full infant tubing system (10mm dia.) including an infant proximal sensor, exhalation cover and membrane to the UUT.

Referring to Figure 7-2 below, connect the open end of the infant proximal sensor to the flow inlet of the pneumatic analyzer. It is recommended that a bacterial filter be used between flow sensor and the flow port in order to protect the test device. If the pneumatic analyzer has a low flow port and exhaust, use them for this test.

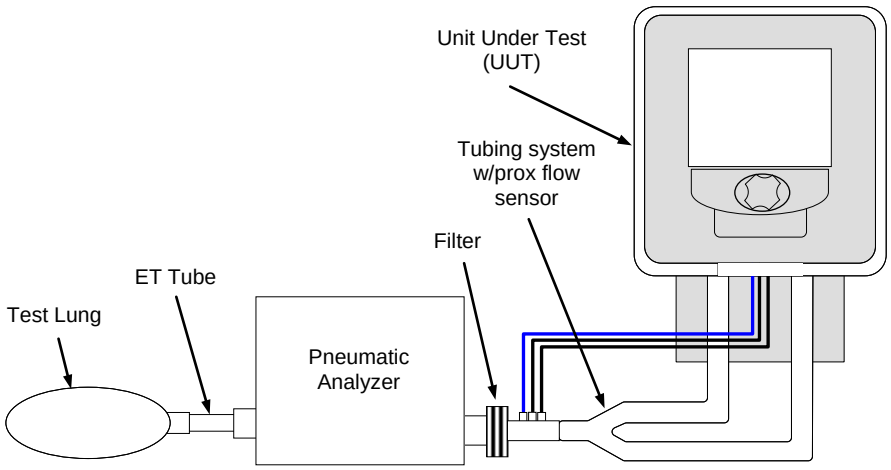


Figure 7-2

Switch the UUT on in normal operation mode and allow power on self test to complete successfully. From the start up screen select the following items:

Gas Supply:*	Air
Patient Type:*	Infant
Prox flow sensor**	On
Humidity Type:	None
Settings:	Standard

***** Menu items may not appear on models set for Infant only.
** May not appear on all software levels.

Select Calibrations in order to access the Calibrations screen. Perform the calibration procedures listed below if necessary referring to the instructions listed in the SELF TEST AND CONFIGURATION SCREENS section of this manual. When instructed to block wye 1 during system test, block the test circuit at the exhaust of the pneumatic analyzer.

- System test
- Flow sensor
- O2 sensor

Select Exit to return to the start up screen and proceed with the testing procedures.

7.10 Performance Test 1 – Gas Volume Accuracy (Vt / Vte / RR)

7.10.1 Infant Volume Check

On the Standby screen of the UUT select Next to proceed to the proposed settings screen and enter the following ventilator settings:

Proposed mode	V-CMV
Trigger type	Pressure
Resp rate	40 b/min
Tidal Volume (Vt)	20 ml
PEEP	5 cmH_2O
Oxygen	21%
Insp Flow Pattern	Decelerate
Peak Flow	6 l/min
T plateau	0.00 s
Auto	Off
Trigger	5.0 cmH_2O
Alarms	Adjust/Auto As Required

Connect an appropriate infant test lung to the flow exhaust port of the pneumatic analyzer. Install a short length of ET tube between the exhaust port and test lung.

Select Start in order to commence ventilation. Allow a minimum of 10 breaths to be delivered before recording any measurements.

Verify the machine cycles with no alarms. If any alarms are active adjust the limits as necessary to eliminate the alarm(s).

On the numeric screen of the pneumatic analyzer verify the delivered tidal volume (Vti) is in the range 20ml ± 3ml. Record test result on the performance verification record.

On the UUT monitoring screen verify the exhaled tidal volume (Vte) is in the range 20ml ± 3ml. Record test result on the performance verification record.

On the numeric screen of the pneumatic analyzer verify the delivered respiratory rate (Rate) in the range 39.5-40.5 b/min.

Press the On/Off key and select Standby from the on screen options in order to return to the Standby screen.

Remove the infant tubing system and infant test lung from the test set up.

7.10.2 Pediatric Volume Check

Connect a full Pediatric tubing system (15mm dia.) including an infant proximal sensor, exhalation cover and membrane to the UUT.

Connect an appropriate adult test lung to the flow exhaust port of the pneumatic analyzer. Install a short length of ET tube between the exhaust port and test lung.

From the Standby screen select the following items:

Main Gas Supply*	Air
Patient *	Pediatric
Prox flow sensor**	On
Humidity Type	None
Settings	Standard

***** Menu items may not appear on models set for Infant only.
** May not appear on all software levels.

Select Calibrations in order to access the Calibrations screen. Perform the calibration procedures listed below, as before when instructed to block wye 1 during system test block at the high flow exhaust of the pneumatic analyzer.

- System test
- Flow sensor

Referring to Figure 7-2, connect the open end of the infant proximal sensor to the flow inlet of the pneumatic analyzer.

Connect an appropriate test lung to the flow exhaust port of the pneumatic analyzer. Place a short length of ET tube between the exhaust port and test lung.

On the Standby screen of the UUT select Next to proceed to the proposed settings screen and enter the following ventilator settings:

Proposed mode	V-CMV
Trigger type	Pressure
Resp rate	30 b/min
Tidal Volume (Vt)	100 ml
PEEP	5 cmH2O
Oxygen	21%
Insp flow pattern	Decelerate
Peak Flow	20 l/min
T plateau	0.00 s
Auto	Off
Trigger	5.0 cmH2O
Alarms	Adjust/Auto As Required

Select Start in order to commence ventilation. Allow a minimum of 10 breaths to be delivered before attempting to record any measurements.

On the numeric screen of the pneumatic analyzer verify the delivered tidal volume (Vti) is in the range 100ml ± 15ml. Record test result on the performance verification record.

On the UUT monitoring screen verify the exhaled tidal volume (Vte) is in the range 100ml ± 15ml. Record test result on the performance verification record.

On the numeric screen of the pneumatic analyzer verify the delivered respiratory rate (Rate) in the range 29.6-30.4 b/min.

Press the On/Off key and then select Standby from the on screen options in order to return to the Stand by screen.

Remove the Pediatric tubing system and test lung from the test set up.

7.10.3 Adult Volume Check

Connect a full adult tubing system (22mm dia.) including an adult proximal sensor, exhalation cover and membrane to the UUT.

From the Standby screen select the following items:

Gas Supply*	Air
Patient Type*	Adult
Prox flow sensor**	On
Humidity Type	None
Settings	Standard

***** Menu items may not appear on models set for Infant only.
** May not appear on all software levels.

Select Calibrations in order to access the calibrations screen. Perform the calibration procedures listed below, as before when instructed to block wye1 during system test block at the flow exhaust of the pneumatic analyzer.

- System test
- Flow sensor

Referring to Figure 7-2, connect the open end of the adult proximal sensor to the flow inlet of the pneumatic analyzer.

Connect an appropriate adult test lung to the flow exhaust port of the pneumatic analyzer. Place short length of ET tube between the exhaust port and test lung.

On the Standby screen of the UUT select Next to proceed to the proposed settings screen and enter the following ventilator settings:

Proposed mode	V-CMV
Trigger type	Pressure
Resp rate	20 b/min
Tidal Volume (Vt)	300ml
PEEP	5 cmH2O
Oxygen	21%
Waveform	Decelerate
Peak Flow	35 l/min
T plateau	0.00 s
Auto	Off
Trigger	5.0 cmH2O
Alarms	Adjust/Auto As Required

Select Start in order to commence ventilation. Allow a minimum of 10 breaths to be delivered before attempting to record any measurements.

On the numeric screen of the pneumatic analyzer verify the delivered tidal volume (Vti) is in the range 300ml ± 25ml. Record test result on the performance verification record.

On the UUT monitoring screen verify the exhaled tidal volume (Vte) is in the range 300ml ± 25ml. Record test result on the performance verification record.

On the numeric screen of the pneumatic analyzer verify the delivered respiratory rate (Rate) in the range 19.7-20.3 b/min.

On successful completion of these testing steps make the following setting changes:

Resp rate	15 b/min
Tidal Volume (Vt)	600 ml
Peak Flow	60 l/min
Alarms	Adjust/Auto As Required

On completion allow a minimum of 10 breaths to be delivered before attempting to record any measurements.

On the numeric screen of the pneumatic analyzer verify the delivered tidal volume (Vti) is in the range 600ml ± 40ml. Record test result on the performance verification record.

On the UUT monitoring screen verify the exhaled tidal volume (Vte) is in the range 600ml ± 40ml. Record test result on the performance verification record.

On the numeric screen of the pneumatic analyzer verify the delivered respiratory rate (Rate) in the range 14.75-15.25 b/min.

On successful completion of these testing steps make the following setting changes:

Resp rate	8 b/min
Tidal Volume (Vt)	1000 ml
Alarms	Adjust/Auto As Required

On completion allow a minimum of 10 breaths to be delivered before attempting to record any measurements.

On the numeric screen of the pneumatic analyzer verify the delivered tidal volume (Vti) is in the range 1000ml ± 60ml. Record test result on the performance verification record.

On the UUT monitoring screen verify the exhaled tidal volume (Vte) is in the range 1000ml ± 60ml. Record test result on the performance verification record.

On the numeric screen of the pneumatic analyzer verify the delivered respiratory rate (Rate) in the range 7.82-8.18 b/min.

On successful completion of these testing steps make the following setting changes:

Resp rate	15 b/min
Tidal Volume	500 ml
Peak Flow	45 l/min
PEEP	5 cmH20
Alarms	Adjust/Auto As Required

Press the Special button on the keypad in order to access special functions. Select SMART SIGH to access sigh settings and make the following setting changes:

Sigh volume	Vt + 50%
Sigh given every	20 Breaths
Multiple Sighs	5 Breaths
Smart Sigh	On

On the UUT monitoring screen verify that after 20 normal cycles the device delivers 5 consecutive breaths at sigh volume. On the numeric screen of the pneumatic analyzer observe that on the 5th of 5 consecutive sigh breaths the volume delivered is in the range 702.5-797.5 ml. Record the result on the performance verification record.

On the UUT monitoring screen verify the Vte reading is in the range 702.5-797.5 ml. Record the result on the performance verification record.

Access the special functions once again switch off SMART SIGH.

7.11 Performance Test 2 – Pressure Accuracy (Pcontrol/PEEP)

7.11.1 Pressure Checks

Adjust the ventilator settings as follows using the proposed settings screen:

Proposed mode	P-CMV
Trigger type	Pressure
Resp rate	8 b/min
PEEP	0 cmH2O
Oxygen	21%
Ti	6.0 s
Pcontrol	10 cmH2O
Auto	Off
Rise Time	Fast
Trigger	5 cmH2O
Alarms	Adjust/Auto As Required

On the proposed settings screen select Start in order to commence ventilation with these new settings. Allow the UUT to deliver 10 breaths before recording any measurements.

Press the Settings button as many times as necessary to access the Apnea backup settings screen and switch apnea back up ventilation to Off.

On the pneumatic analyzer screen record the displayed peak airway pressure and verify that it is in the range 10cmH2O ± 2.25cmH2O. Record the result in the performance verification record.

On successful completion of these testing steps make the following setting changes:

Resp rate	8 b/min
Ti	6.0 s
Pcontrol	50 cmH2O
Alarms	Adjust/Auto As Required

On the pneumatic analyzer screen record the displayed peak airway pressure and verify that it is in the range 50cmH2O ± 3.25cmH2O. Record the result in the performance verification record.

On successful completion of these testing steps make the following setting changes:

Pcontrol	10 cmH2O
Alarms	Adjust/Auto As Required

Press the Special button on the keypad in order to access special functions. Select SMART SIGH to access sigh settings and make the following setting changes:

Sigh pressure	Pcontrol + 50%
Sigh given every	20 Breaths
Multiple Sighs	5 Breaths
Smart Sigh	On

On the UUT monitoring screen verify that after 20 normal cycles the device delivers 5 consecutive breaths at sigh pressure.

Observe the numeric screen of the pneumatic analyzer and verify a peak pressure during inspiration of 15cmH20 ± 2.375cmH2O. Record the result on the performance verification record.

Access the special functions once again switch off smart sigh. Proceed to next step.

Adjust the ventilator settings as follows using the proposed settings screen:

Proposed mode	P-CMV
Trigger type	Pressure
Resp rate	8 b/min
PEEP	5 cmH2O
Oxygen	21%
Ti	1.00 s
Pcontrol	5 cmH2O
Auto	Off
Rise time	Fast
Trigger	5.0 cmH2O
Alarms	Adjust/Auto As Required

On the numeric display of the pneumatic analyzer observe and record the displayed PEEP measurement. Verify the reading is in the range 5cmH2O ± 2.2cmH2O. Record the result on the performance verification record.

Adjust the ventilator settings as follows:

PEEP	30 cmH2O
Alarms	Adjust/Auto As Required

On the numeric display of the pneumatic analyzer observe and record the displayed PEEP measurement. Verify the reading is in the range 30cmH2O ± 3.2cmH2O. Record the result on the performance verification record.

On successful completion of these testing steps adjust the ventilator settings as follows:

PEEP	50 cmH2O
Alarms	Adjust/Auto As Required

On the numeric display of the pneumatic analyzer observe and record the displayed PEEP measurement. Verify the reading is in the range 50cmH2O ± 4.0cmH2O. Record the result on the performance verification record.

Press the On/Off key and then select Standby from the on screen options in order to return to the Stand by screen.

7.12 Performance Test 3 – Oxygen Delivery Accuracy

On the pneumatic analyzer identify the display for measured oxygen, if the pneumatic analyzer does not offer oxygen monitoring an additional FiO_2 monitor should be added to the patient circuit after the proximal sensor.

On the Standby screen of the UUT select Next to proceed to the proposed settings screen and enter the following ventilator settings:

Proposed mode	P-CMV
Trigger type	Pressure
Resp rate	30 b/min
PEEP	0 cmH2O
Oxygen	21%
Ti	1.00 s
Pcontrol	10 cmH2O
Auto	Off
Rise time	Fast
Trigger	5.0 cmH2O
Alarms	Adjust As Required

On the proposed settings screen select Start in order to commence ventilation with these new settings. Allow a minimum of two minutes after activation of settings for the O_2 readings to stabilize. Verify the O_2 reading on the test monitor is 21% ± 3%. Verify the O_2 reading on the UUT is 21% ± 6%. Record the measurements on the performance verification record.

On successful completion of the test adjust the ventilator settings as follows:

Oxygen	60%
Alarms	Adjust As Required

Allow a minimum of two minutes after activation of settings for the O_2 readings to stabilize. Verify the monitored O_2 reading on the test monitor is 60% ± 3%. Verify the O_2 reading on the UUT is 60% ± 6%. Record the measurements on the performance verification record.

On successful completion of the test adjust the ventilator settings as follows:

Oxygen	100%
Alarms	Adjust As Required

Allow a minimum of two minutes after activation of settings for the O_2 readings to stabilize. Verify the O_2 reading on the test monitor is 100% ± 3%. Verify the O_2 reading on the UUT is 100% ± 6%. Record the measurements on the performance verification record.

Press the On/Off key and then select Standby from the on screen options in order to return to the Stand by screen.

Remove the pneumatic analyzer from the test set up and connect the test lung and ET tube directly to the proximal flow sensor.

7.13 Performance Test 4 – Alarm Operation

On the Standby screen of the UUT select Next to proceed to the proposed settings screen and enter the following ventilator settings:

Proposed mode	V-CMV
Trigger type	Pressure
Resp rate	15 b/min
Tidal Volume (Vt)	500 ml
PEEP	0 cmH2O
Oxygen	21%
Insp flow pattern	Decelerate
Peak Flow	45 l/min
Tplateau	0.00 s
Auto	Off
Trigger	5.0 cmH2O
Alarms	Adjust As Required

Remove the adult test lung and ET tube from the proximal sensor outlet and leave the port open to atmosphere.

Verify that after a small number of breaths the high priority audible alarm is enunciated. Further verify that it is accompanied by a flashing alarm LED and the Disconnect alarm message is visible on screen. Record the test result on the performance verification record.

Press the Alarm Mute button only once; on pressing confirm the audible alarm is silenced but the visual alarm indicators remain active. Record the test result on the performance verification record.

Press the Alarm Mute button again and confirm the audible alarm is active once more and the visual alarm indicators remain active. Record the test result on the performance verification record.

Press the Alarm Mute button once again and confirm the audible alarm is silenced and after a period of 108-132 seconds is active once more. Record the test result on the performance verification record.

Reconnect the adult test lung and ET tube to the proximal sensor. Verify the Disconnect and all appended alarm conditions cancel after a number of breaths. Record the test result on the performance verification record.

Remove the test lung and ET tube from the proximal sensor and occlude the open port of the proximal sensor.

Verify that after a small number of breaths the high priority audible alarm is annunciated. Verify it is accompanied by a flashing alarm LED, the High Pressure alarm message is visible on screen and that breath delivery truncates upon hitting the high pressure alarm limit. Record the test result on the performance verification record

Remove the occlusion from the proximal sensor and reconnect the adult test lung and ET tube. Verify that after a small number of breaths all alarm conditions auto reset.

Press the settings key as many times as necessary to access the apnea settings screen. Set the apnea back up parameters as follows:

Proposed mode	P-CMV
Trigger type	Pressure
Resp rate	15 b/min
PEEP	5 cmH2O
Oxygen	21%
Apnea backup	On
Ti	1.00 s
Pcontrol	20 cmH2O
Time	20 s
Rise time	Slow
Trigger	5.0 cmH2O

Press the Settings key as many times as necessary to access the proposed settings screen.

On the proposed settings screen select SPONT mode and leave the remaining settings at their existing levels. Select Start to initiate the mode change.

Verify that after a period of 17-23 seconds a high priority audible alarm is enunciated and it is accompanied by the alarm LED and an Apnea alarm message on the screen. Record the test result in the performance verification record.

Verify that apnea back up ventilation has been initiated at the settings programmed from the table above. Record the test result in the performance verification record.

On the test lung simulate two patient inspiratory efforts within a 10 second period. Verify that apnea back ventilation discontinues and that SPONT mode is restored. Record the test result in the performance verification record.

7.14 Performance Test 5 – Gas Sources

Press the settings key in order to proceed to the proposed settings screen. Adjust the settings on screen as follows and then press Start to initiate the changes.

Proposed mode	V-CMV
Trigger type	Pressure
Resp rate	15 b/min
Tidal Volume (Vt)	500 ml
PEEP	0 cmH2O
Oxygen	40%
Insp flow pattern	Decelerate
Peak Flow	45 l/min
Tplateau	0.00 s
Auto	Off

Trigger	5.0 cmH2O
Alarms	Adjust As Required

Disconnect the high pressure oxygen hose from the source and observe the UUT for its response.

After a number of cycles verify that a medium priority alarm is enunciated and that it is accompanied by a flashing alarm LED and an Oxygen Supply alarm message. Verify that ventilation continues uninterrupted.

After an additional number of cycles verify that a high priority alarm is enunciated and it is accompanied by a flashing alarm LED and a Low Oxygen alarm message. Verify that ventilation continues uninterrupted.

Reconnect the high pressure oxygen hose to the source and verify that after a number of breaths each of the above alarm conditions reset. Record the test result on the performance verification record.

7.14.1 Units with Internal Compressor Only

Disconnect the high pressure air hose from the source and observe the UUT for its response.

Verify that a medium priority air supply alarm is annunciated after which the internal compressor system starts. Verify also that an information message FIO2 and delivery can vary is displayed on screen.

Reconnect the high pressure air hose to the source and verify the internal compressor system ceases to operate and any alarms reset. Record the test result on the performance verification record.

Switch the UUT off, and then on once more in the user configuration menu. Enter the appropriate access code and on configuration screen 1 set Compressor backup to Off. Switch the UUT off once more.

Switch the UUT on and allow it to complete POST. Select Standard settings and then Next to proceed. On the proposed settings screen select Start to commence ventilation. Adjust alarm limits as necessary to eliminate any nuisance alarm events.

7.14.2 All Units

Disconnect the high pressure air hose from the source once more. Observe the UUT for its response.

After a number of cycles verify that a medium priority alarm is enunciated and that it is accompanied by a flashing alarm LED and an Air Supply alarm message. Verify that ventilation continues uninterrupted.

After an additional number of cycles verify that a high priority alarm is enunciated and that it is accompanied by a flashing alarm LED and a High Oxygen alarm message. Again verify that ventilation continues uninterrupted.

Disconnect the high pressure oxygen hose from the source. Observe the device once more and verify that after a number of breaths a high priority Internal Pressure Low alarm message is displayed, and that after a further number of breaths breath delivery ceases.

Reconnect both high pressure hoses to the appropriate sources. Verify that breath delivery is restored and that all alarms conditions reset. Record the test result on the performance verification record.

If applicable, enter configuration screen 1 and set the Compressor backup to On.

7.15 Troubleshooting Performance Verification

Test	Description	Corrective Action
Volume Accuracy:		
Tidal Volume Readings	Tidal Volume Readings Out of Range High/Low	1. Perform system test with the pneumatic analyzer in line to calculate the system compliance and leak. 2. Verify correct compliance and resistance in use on lung simulator.
Exhaled Tidal Volume Readings	Exhaled Tidal Volume Reading Out of Range High/Low	1. Perform system test with the pneumatic analyzer in line to calculate the system compliance and leak. 2. Ensure an ET tube is installed between the flow sensor and test lung. 3. Ensure correct orientation of proximal sensor and sensing lines. 4. Perform flow sensor calibration. 5. Replace proximal flow sensor 6. Verify internal calibration of PV1 and flow sensor.
Respiratory Rate Readings	Respiratory Rate Readings out of range high/low. (Auto-cycling)	1. Verify trigger type and setting. 2. Perform system test to ensure no leakage from system. 3. Re-zero pressure transducers. 4. Replace Sensor board.

Pressure Accuracy:		
Inspiratory Pressure Readings	Inspiratory Pressure readings out of range High/Low	1. Ensure correct configuration compliance / resistance on lung simulator. 2. Re-zero all pressure transducers. 3. Performed System Test. 4. Replace PV1 Valve 5. Replace PV2 exhalation valve.
PEEP Pressure Reading	PEEP Pressure out of range	1. Ensure correct configuration compliance / resistance on lung simulator. 2. Re-zero all pressure transducers. 3. Performed System Test. 4. Replace PV2 exhalation valve.
Oxygen Delivery:		
Pneumatic analyzer O_2 Reading	O_2 reading out of range on pneumatic analyzer.	1. Perform full two point calibration of Pneumatic analyzer O_2 sensor.
Vent O_2 Reading	O_2 reading out of range on ventilator.	1. Perform calibration of the ventilators O_2 sensor. 2. Replace O_2 sensor. 3. Perform FabTest 7 (Sensor adjust)
Alarm Operation:		
Disconnect	Disconnect alarm is not active	1. Ensure that test lung has been removed from the wye. 2. Verify that alarm settings are appropriate.
Alarm Silence	Alarm silence is not active	1. Press alarm silence key again and verify appearance of icon in display screen. 2. Verify operation of the alarm silence key using FabTest 2. 3. Replace Lexan.
High Pressure	High pressure alarm is not active	1. Ensure that the wye is fully occluded. 2. Verify that alarm settings are appropriate.
Apnea	Apnea alarm is not active	1. Verify the ventilator settings, ensure that device is set to Spont mode and that apnea parameters are appropriately set. 2. Observe monitored data and ensure that monitored respiratory rate is 0.

Apnea Back Up	Apnea back up ventilation is not active.	1. Verify the ventilator settings. Ensure that apnea back up is set to On. 2. Observe monitored data and ensure that monitored respiratory rate is 0.
Gas Sources:		
O2 Supply Alarm	O2 supply alarm not active	1. Ensure that O2 supply has been disconnected.
Compressor Not Available	Compressor not active at removal of air supply	1. Ensure that Compressor back up is switched to on in configuration. 2. Ensure that compressor harness is secure. 3. Replace compressor
Compressor Stalls	Compressor stops during operation.	1. Verify operation of compressor unloading valve. 2. Ensure that exhaust is audible. 3. Check compressor inlet filter 4. Replace unloading valve. 5. Replace compressor.
Air Supply Alarm	Air supply alarm not active	1. Ensure that Air supply has been disconnected. 2. Ensure that compressor back up is switched to off in configuration.

Section

8

DIAGNOSTIC ERROR CODES and ALARM MESSAGES

8.1 Introduction

This section of the Inspiration series technical manual is provided to allow the service technician to interpret all error codes and general faults.

8.1.1 About Diagnostic Codes

During power on self test (POST) or during ongoing diagnostic routines, in the event of a hardware or software error is detected, which may compromise safe breath delivery, the device annunciates an alarm and logs an error code in the following form:

TF-XY where TF = Technical Fault

XY = Specific Error Number/Type

In the event of a technical error being detected the device will initiate the appropriate high priority alarm signals to highlight the issue. At the same time power is immediately removed from the device's pneumatic system, de-energizing all valves and putting the device into a safety valve mode (see Section 4.7.5 Safety Valve (SV). The device remains in safety-valve-open mode until the triggering condition has been corrected and the unit has been tested.

When investigating any error condition review the full error log (FabTest 11) in order to establish if there are any contributory problems and whether there is a prolonged history of the reported problem.

When viewed in FabTest 11 error log technical errors are highlighted with an asterisk (*).

8.1.2 Technical Errors

Refer to the following table for a detailed breakdown of all technical errors, their cause and probable steps toward resolution. The probable steps are sequenced in order of the most probable malfunction in order to give the most efficient corrective action.

It is possible the suggested steps may not always provide a fix to the particular problem. Should this occur refer to your local technical support provider for further recommendations.

8.1.3 Technical Error Listing and Troubleshooting

In event a problem is detected during the POST routines the device is either not able to continue with the first part start sequence and therefore freeze or on completion will display an error code specific to the condition detected in the second part of the start sequence. The respective error codes along with a definition and troubleshooting recommendations are included here below:

Error no.	Error description	Effect	Corrective Action
Freeze	Processor, RAM or ROM is defective	Ventilator cannot start	1. Verify all ribbon cable connections. 2. Reinstall System Software 3. Replace Processor Board
TF 1	1. Checksum error 2. Defective processor	Configuration EEPROM memory defective – Motherboard	1. Replace Motherboard 2. Replace Processor Board
TF 2	1. Checksum error 2. No communication with Sensor board 3. Defective processor	Configuration EEPROM memory defective – Sensor board	1. Ensure Sensor board ribbon cable connections. 2. Ensure Motherboard Main ribbon cable connections 3. Replace Sensor Ribbon Cable 4. Replace Motherboard Ribbon Cable 5. Replace Sensor board 6. Replace Processor Board
TF 3	Sensor gains calibration values integrity check violation	Sensor gains not valid Sensor board EEPROM	1. Check in FabTest 12 if temp drift cal is valid - perform drift cal if necessary 2. Replace Sensor board
TF 4	1. Checksum Error 2. no communication with Sensor board 3. Defective processor	Configuration EEPROM memory defective – Power board	1. Ensure Sensor ribbon cable connections 2. Replace Motherboard ribbon cable 3. Replace Power board 4. Replace Processor Board
TF 5	1. Checksum Error	NVRAM defective or NVRAM battery empty	1. Perform Checksum test on NVRAM, FabTest 3 2. Clear & test NVRAM. Record vent configurations as vent is set to default valves and will need to be reconfigured and fully recalibrated 3. Replace NVRAM lithium battery 4. Replace Motherboard
TF 6	Unable to save log entry	NVRAM defective	1. Perform Checksum test of NVRAM, FabTest 3 2. Clear & test NVRAM. Record vent configurations as vent is set to default valves and will need to be reconfigured and fully recalibrated 3. Replace Motherboard

Error no.	Error description	Effect	Corrective Action
TF 7	Pressure sensors offset values integrity check violation	Pressure sensor offsets not valid in NVRAM	1. Perform re-zero of all pressure transducers (FabTest 5) 2. Replace Sensor board 3. Replace Motherboard 4. Replace Power board
TF 8	Flow sensors values integrity check violation	Internal flow sensors data in NVRAM not valid	1. Recalibrate internal flow sensors (FabTest 7) 2. Perform Checksum test on NVRAM, FabTest 3 3. Clear & test NVRAM. Record vent configurations as vent is set to default valves and will need to be reset. Fully recalibrate 4. Replace Motherboard
TF 9	Altitude compensation value integrity check violation	Altitude compensation data in NVRAM not valid	1. Set appropriate altitude compensation value in configuration screen 1 2. Replace Sensor board
TF 10	Not used		
TF 11	Power processor SW version check	SW version of power processor and system processor not compatible	1. Ensure that power and system software are at compatible revisions 2. Ensure Motherboard ribbon cable is seated correctly on both sides 3. Load appropriate Power and/or System software 4. Replace Power board
TF 12	1. AD converter 1 setup invalid 2. Connection with AD converter 1 lost	Data not valid from ADC 1	1. Check in FabTest 2 to identify if the connection is lost completely or if the setup is invalid 2. Ensure Sensor ribbon cable is seated correctly on both sides 3. Ensure Motherboard ribbon cable is seated correctly on both sides 4. Replace Sensor ribbon cable 5. Replace main ribbon cable 6. Replace Sensor board 7. Replace Processor Board 8. Replace Power board

Error no.	Error description	Effect	Corrective Action
TF 13	1. AD converter 2 setup invalid 2. Connection with AD converter 2 lost	Data not valid from ADC 2	1. Check on FabTest 2 to identify if the connection is lost completely or if the setup is invalid 2. Ensure Sensor ribbon cable is seated correctly on both sides 3. Ensure Controller ribbon cable is seated correctly on both sides 4. Replace Sensor ribbon cable 5. Replace main ribbon cable 6. Replace Sensor board 7. Replace Processor Board 8. Replace Power board
TF 14	Difference of reference voltage of ADC1 to ADC2 out of range	Sensor board: Values of ADC1 and ADC 2 not valid	1. Ensure Sensor ribbon cable is seated correctly on both sides 2. Replace Sensor ribbon cable 3. Replace Sensor board
TF 15	Source voltage of amplifiers out of range	Sensor board: Values of ADC 1 not valid	1. Error code may appear if unit is left on (in stand-by), is not plugged into AC mains, and batteries discharge 2. Ensure Sensor ribbon cable is seated correctly on both sides 3. Replace Sensor ribbon cable 4. Replace Sensor board 5. Replace Power board
TF 16	Source voltage of amplifiers out of range	Sensor board: Values of ADC2 not trustable	1. Error code may appear if unit is left on (in stand-by), is not plugged into AC mains, and batteries discharge 2. Ensure Sensor ribbon cable is seated correctly on both sides 3. Replace Sensor ribbon cable 4. Replace Sensor board 5. Replace Power board
TF 17	Supply voltage for AD conversion out of range	Sensor board: Supply voltage out of range	1. Ensure Sensor ribbon cable is seated correctly on both sides 2. Replace Sensor ribbon cable 3. Replace Sensor board 4. Replace Power board
TF 18	SW Error	Memory addressing out of bounds	1. Re-install system software 2. Replace Processor Board

Error no.	Error description	Effect	Corrective Action
TF 19	Communication with power processor lost	No valid data from Power Processor and no supervision of system processor	1. Ensure Motherboard ribbon cable is seated correctly on both sides 2. Reset Power processor by pressing SW3 on Power board) 3. Re-install Power processor software 4. Replace Motherboard ribbon cable 5. Replace Power board 6. Replace Processor Board
TF 20	1. Improper calibration 2. HW damage	Value of pressure sensor P2 out of range	1. Perform re-zero of all pressure transducers. (FabTest 5) 2. Replace Sensor board
TF 21	1. Improper calibration 2. HW damage	Value of pressure sensor dP2 out of range	1. Perform re-zero of all pressure transducers.(FabTest 5) 2. Replace Sensor board
TF 22	Not used		
TF 23	Not used		
TF 24	Software tasks corruption	Operating system error	1. Re-install system software 2. Replace Processor Board
TF 25	Software tasks overflow	Operating system error	1. Re-install system software 2. Replace Processor Board
TF 26	Not used		
TF 27	PV1 offset or gain integrity check violation	PV1 valve data not valid in NVRAM	1. Is Correct PV1 model selected (see Manufacturing Config 1)? 2. Perform calibration of PV1 (FabTest 9) 3. Replace Power board 4. Replace Motherboard
TF 28	Temp sensor failure	Difference between temperature sensors too large	1. Access FabTest 2 and verify reading from temperature sensors 2. Replace Sensor board 3. Replace Power board
TF 29	Incompatible rev of Sensor board	Old Sensor board with Rev 1 to 3 is installed	1. Replace Sensor board with a newer revision

8.2 General Error Listing

8.2.1 Introduction

This section of the Inspiration series technical manual is provided to allow the trained service technician to interpret the alarm messages which may occur during normal operation of the device and which may be recorded in the devices alarm log.

8.2.2 Alarm Log

The alarm log provides the user with a listing of the last 100 alarm events recorded in chronological order along with the date and time of the occurrence. The alarm log is accessed through the alarm menu screen which may be entered at any time by pressing the Alarm key on the ventilator's front panel. The content of the alarm log is retained when the ventilator is switched off. When the ventilator is switched on and the Last settings are selected, any alarm events that have been recorded in the alarm log are available. The contents of the alarm log are cleared by selecting Standard settings from the Standby screen during power on.

The alarm log in FabTest 11 (Diagnose) provides the trained technician with a listing of the last 500 alarm events recorded in chronological order along with the date and time of the occurrence. The content of this Alarm log is retained when the ventilator is switched off and cannot be cleared.

8.2.3 Settings Log

The settings log provides the user with a listing of the last 1573 setting change events recorded in chronological order along with the value before and after the change if possible. The settings log may be accessed through the FabTest 11 (Diagnose) screen. The content of the settings log is retained when the ventilator is switched off. The contents of the settings log cannot be cleared. The settings are referenced by an internal unique number. This log is planned to be used solely by eVent Medical or an authorized person in case of a hazard.

8.2.4 Audible Alarms

All audible and visual alarms on the Inspiration ventilator comply with the requirements of EN475; the audible signals used are as follows:

High Priority Alarms	Five signals, repeated periodically
Medium Priority Alarms	Three signals, repeated periodically
Information Messages	One signal, one time

Audible alarms may be silenced for a period of 120 seconds (2 minutes); this is done by a single press of the Alarm Mute key on the device's front panel. Once this time has elapsed any active audible alarm re-sounds. During the silence period any new alarm that is triggered immediately terminates the alarm silence.

A pre-alarm silence function may be enabled by pressing and holding the Alarm Mute key for a period of approximately 1 second. Its enabling is verified by the presence of a red background to the on screen alarm mute indicator. With this function enabled all audible alarms are silenced for a period of 120 seconds (2 minutes). Should any new alarms occur during the silence period the Alarm LED flashes, and an alarm message with appropriate priority is displayed in the screen area.

8.2.5 Alarm Signals

Along with individual audible signals, each alarm type is easily recognizable by its visual characteristics. These are defined as follows:

Priority	Background Color	Audible Signal	Alarm LED Frequency	Nurse Call Status	Can be Reset by the user
High	Red	5 signals repeated	2.0 Hz	Enabled	No
Medium	Yellow	3 signals repeated	0.5 Hz	Enabled	No
Information	White	one signal	N/A	Disabled	No

8.3 High Priority Alarms

The following is a full list of alarms, classified as a high priority. In each case a description of the error and the ventilator response is listed:

Error No	Alarm Message	Description of Error	Ventilator Response
40	Battery Flat	Internal rechargeable battery is flat.	Device switches to ambient breathing mode (Safety valve open)
41	Occlusion	Pressure at the start of inspiration is too high.	Ventilation continues with inspiration valve closed.
42	High Pressure	Patient system pressure has reached the high pressure alarm setting.	Ventilator immediately switches to exhalation. Ventilation continues but pressure is limited at the alarm setting.
43	Internal Pressure Low/Disconnect	Pressure within the gas reservoir is too low	Ventilation continues, nebulizer is switched off
44	Low Pressure	Pressure cannot be attained in the patient breathing circuit, possible due to a leak or disconnect.	Ventilation continues
45	Apnea	The set apnea interval has elapsed without a patient triggered or mandatory breath being delivered as set in the Apnea settings screen. Is active in V-SIMV, P-SIMV, PRVC-SIMV and Spontaneous modes (SPONT, VS).	Device will look for patient's next inspiratory effort. After two consecutive spontaneous breaths the ventilator switches over to normal ventilation. Note: If apnea back-up is switched to off in the apnea back-up screen, apnea alarm is triggered but back up ventilation does not occur.

Error No	Alarm Message	Description of Error	Ventilator Response
46	Low Minute Volume	Exhaled minute volume is too low compared with the set alarm limit for ExpMinVol. Note: If proximal sensor is switched to off in the configuration section, inspired minute volume (InspMinVol) is showed instead	Ventilation continues
47	High Minute Volume	Exhaled minute volume is too high compared with the set alarm limit for ExpMinVol. Note: If proximal sensor is switched to off in the configuration section, inspired minute volume (InspMinVol) is showed instead	Ventilation continues
48	Disconnection	Disconnection of patient	Ventilation continues
49	Low Oxygen	Inspiratory O_2 concentration is too low. Possible causes: gas mixing system error, O_2 cell faulty, monitor value too low compared with the control value, O_2 sensor calibration should be performed.	Ventilation continues
50	High Oxygen	Inspiratory O_2 concentration is too high. Possible causes: gas mixing system error, O_2 cell faulty, monitor value too high compared with the control value, O_2 sensor calibration should be performed.	Ventilation continues
51	Not currently used		

Error No	Alarm Message	Description of Error	Ventilator Response
52	Low Tidal Volume	Exhaled tidal volume is too low compared with the set alarm limit for Vte. Note: If proximal sensor is switched to off in the configuration section, inspired breath volume (Vti) is showed instead	Ventilation continues
53	High Tidal Volume	Exhaled tidal volume is too high compared with the set alarm limit for Vte. Note: If proximal sensor is switched to off in the configuration section, inspired breath volume (Vti) is showed instead	Ventilation continues
54	Apnea Back Up Active	The apnea interval has elapsed without a patient triggered or mandatory breath being delivered. Apnea back-up ventilation has been commenced.	Ventilator will switch to settings as defined in apnea setting screen.
55	Speaker Fault	A fault has been detected with the main alarm speaker.	Ventilation continues unaffected but with continuous tone audible alarm.
56	Not currently used		
57	Not currently used		
58	Prox. Line On Right Side Port?	Disconnection of pressure line of patient mask Note: Only active if NCPAP is active	Flow continues
59	Heliox pressure Low - Using Air	Heliox high pressure source is empty, air from the internal compressor is used instead Note: This alarm only occurs if Heliox is switched on	Ventilation continues Device switches over to pressure triggering mode

Error No	Alarm Message	Description of Error	Ventilator Response
60	Heliox Supply	Heliox high pressure source is empty, the other high pressure source is used instead Note: This alarm only occurs if Heliox is switched on	Ventilation continues
	TF-XX	A technical error has occurred; refer to section 7 for further details.	Device switches to ambient breathing mode (Safety valve open)
61-69	Not currently used		

Note:

All exhaled volume monitoring is performed by the ventilator's proximal flow sensor, therefore alarms for high/low exhaled tidal and exhaled minute volumes are disabled when the proximal flow sensor has been switched off.

Note:

As all oxygen monitoring is performed by the ventilators internal oxygen cell, alarms for high/low oxygen are disabled when the oxygen sensor has been switched off.

8.4 Medium Priority Alarms

The following is a full list of alarms, classified as medium priority. In each case a description of the error and the ventilator response is listed:

Error No.	Alarm Message	Description of Error	Ventilator Response
70	Not currently used		
71	Vti Limit Reached	Delivered volume is being limited by Vti Limit alarm settings	Ventilation continues with delivered volume limited.
72	Air Supply	The air supply has been interrupted and back-up compressor is switched off in the configuration menu.	Ventilation continues with 100% Oxygen, where possible.
73	Oxygen Supply	The oxygen supply has been interrupted.	Ventilation continues with air supply (21%).
74	Compressor	The internal compressor has failed.	Ventilation continues with 100% oxygen, where possible.
75 - 76	Not currently used		
77	High frequency	Respiratory rate is too high when compared with the high rate alarm limit.	Ventilation continues

Error No.	Alarm Message	Description of Error	Ventilator Response
78	Low frequency	Respiratory rate is too low when compared with the low rate alarm limit.	Ventilation continues.
79	Not currently used		
80	Check Pcontrol / Pmax	Pcontrol and/or high-pressure alarm settings are incorrect i.e. Pcontrol > high-pressure alarm setting.	Ventilation continues Pressure is limited at the high-pressure alarm setting until the settings are corrected.
81	Check Psupport / Pmax	Psupport and/or high-pressure alarm settings are incorrect i.e. Psupport > high-pressure alarm setting.	Ventilation continues Pressure support is limited at the high-pressure alarm setting until the settings are corrected.
82	Not currently used		
83	Battery Low	Internal battery voltage is too low. Make sure that there is an alternative source of power available	Ventilation continues
84	High Temperature	The temperature inside the device is too high.	Ventilation continues.
85	High external voltage	The external DC supply voltage is too high.	Ventilation continues
86	Pmean Low	Patient system mean pressure is too low compared with the set alarm limit for Pmean.	Ventilation continues
87	Pmean High	Patient system mean pressure is too high compared with the set alarm limit for Pmean.	Ventilation continues
88	High Leak Rate	Monitored value for Leak % is too high compared with the set alarm limit for Leak %.	Ventilation continues
89	Not currently used		

Error No.	Alarm Message	Description of Error	Ventilator Response
90	Volume not delivered	Upper limit of operational pressure for VTV ventilation reached, further increase not possible (Pop high = Ppeak alarm – 5mbar)	Ventilation continues. Volume delivered is maybe too low
91-109	Not currently used		

8.5 Low Priority Alarms

There are no alarms classified as a low priority.

8.6 Information Messages

The following are information messages which may be observed on the device. In each case a description of the message and the ventilator response is listed:

Error No	Message	Description of Information	Ventilator Response
110	Not currently used		
111	Battery Not Available	The internal battery is not available. Possible causes: battery flat, battery missing, faulty cable connections.	Ventilation Continues
112	Logbook Cleared	Standard ventilator settings have been selected during start up. Alarm Log has been cleared.	Ventilation Continues.
113	Memory CPU not protected	EEPROM on the Motherboard is not write protected	Ventilation Continues
114	Memory sensor not protected	EEPROM on the Sensor board is not write protected	Ventilation Continues
115	Memory power not protected	EEPROM on the Power board is not write protected	Ventilation Continues
116	Flow trigger not available	Flow triggering is not available. Possible causes: loss of wall air source	Device switches over to a pressure trigger mode.
117	Nebulizer not available	Nebulizer is not available. Possible cause: Flow delivered is too low to allow nebulizer function	The nebulizer is switched off.

Error No	Message	Description of Information	Ventilator Response
118	100% O2 not available	100% O2 function is not available. Possible causes: oxygen supply not available while 100% O2 is being administered or O2 calibration has been started.	100% O2 cannot be started and is therefore not displayed on the monitor.
119	Not currently used		
120	Flow calibration not available	The flow sensor cannot be calibrated because it is disabled in the configuration menu.	Flow calibration interrupted.
121	100%O2 calibration not available	Acquired calibration data is out of allowed range Possible causes: oxygen supply empty or O2 cell faulty	Ventilation continues O2 calibration is interrupted
122	Gas Supply connected; Heliox?	Shows up after switching over from air to Heliox to make sure that Heliox has been connected	Flow correction for Heliox is activated
123	Inverse ratio set	Ventilation settings have been set to an inverse ratio (Exhalation time > Inhalation time)	Ventilation continues

Section

9

SERVICE AND REPAIR

9.1 Introduction

This section of the Inspiration series technical manual describes how to repair the ventilator's major subassemblies and their components. The repair procedures include removal and installation as applicable.

This section does not provide a complete breakdown of all assemblies and complete disassembly rather disassembly to what the manufacturer deems necessary and reasonable. Repair procedures are provided for all major assemblies and a complete illustrated parts breakdown is included in section 10 of this manual.

9.2 Repair Safety

When servicing the Inspiration ventilator system, be sure to familiarize yourself with and adhere to all posted and stated safety warning and caution labels on the ventilator and its components. Failure to adhere to such warnings at all times may result in injury or property damage

To prevent patient injury do not use the ventilator if it requires repair.

To prevent personal injury or death, do not attempt any service to the ventilator while a patient or other person is connected to it.

To prevent electric shock hazard always ensure that all electrical power has been removed from the device prior to commencing service. This statement requires that not only mains power is removed but also the device's internal batteries and any external DC source is also removed as applicable. If the device must be serviced with the power connected, be careful to avoid electrical shock. At all times follow accepted safety practices for electrical equipment when performing any repairs.

To prevent possible personal injury, always ensure that high pressure air and oxygen sources have been removed.

To prevent possible personal injury and equipment damage never attempt to push or pull a ventilator installed on its stand with the brakes set.

To prevent possible personal injury and equipment damage always ensure the brakes are set to prevent inadvertent movement when performing service.

9.3 Repair Guidelines

The following general guidelines should be considered at all times when performing service to the Inspiration ventilator system.

Follow repair safety guidelines at all times.

The majority of hardware on the ventilator is metric sized. Some Cart choices have S.A.E standard hardware. Always ensure the correct tools are used when performing service. The use of incorrect tooling may result in damaged hardware.

To prevent any possible damage caused by electrostatic discharge always ensure that appropriate ESD guidelines and precautions are followed when performing service to the equipment.

Use only recommended tools, test equipment, service materials, and parts when servicing the ventilator.

When performing service, take precautions to prevent dirt and other particles from entering the ventilator interior, particularly the pneumatic manifold assemblies.

Inspect any removed parts including those removed to gain access to a suspected faulty component. Inspect and clean the exposed area behind removed parts as required. Clean any removed parts to facilitate further inspection.

Investigate and determine the cause of any detected abnormality. Repair the unit or consult your local eVent Medical technical support location for assistance on unsolved problems.

Replace or repair any parts which are found to be worn, missing, damaged, cracked, incorrect, or otherwise show signs of any physical abnormalities.

9.4 Cleaning

If needed, follow these general cleaning guidelines when cleaning the ventilator during servicing. The procedures for periodic cleaning and sterilization of the ventilator and accessories are listed in the Inspiration ventilator system User Manual. Specific procedures for periodic cleaning and inspection done during the ventilators performance verification are listed in the relevant section of this manual.

Clean ventilator exterior surfaces before disassembly. Use isopropyl alcohol, a bactericidal agent, or a mild detergent and warm water solution; combined with a clean, lint-free cotton cloth. Do NOT apply liquid cleaner directly to the surface of the ventilator. Apply liquid cleaners to the cloth, then wipe the ventilator and accessories clean.

Vacuum ventilator interior using ESD-safe equipment. Do NOT clean the ventilator interior with high pressure air.

During disassembly, clean parts as necessary with one of the above cleaners. Any excessively dirty items which cannot be cleaned should be replaced.

9.5 Electrical Cables and Pneumatic Connection

To ensure correct reassembly of the device, take note of or label wire and tube positions before disconnecting parts. Make sure that all tubes and harnesses are correctly installed and do not interfere with and cannot be damaged by any moving parts

9.6 ESD Control

It is important to follow appropriate ESD control procedures whenever the ventilator system is being serviced.

9.6.1 General Information

ESD can permanently damage ESD-sensitive microelectronic components or assemblies when they are handled and even when no direct contact is made with the component or assembly. ESD damage may not be immediately apparent, however, ESD damage will show up at a later time, either as a premature failure of a component or assembly, or as an intermittent failure, which can be difficult and time consuming to locate.

9.6.2 Procedures and Precautions

Follow these minimum procedures and precautions to prevent ESD damage to the ESD sensitive microelectronic components and assemblies of the Inspiration ventilator system.

Use a personnel grounding system. Before opening the ventilator enclosure, ensure that a personnel grounding system (incorporating wrist strap, static-dissipative mat and ground cord) is worn correctly and is properly connected to reliable ground.

Follow correct procedures for use of static dissipative mat. Place tools, test equipment and the ESD sensitive device on the mat before starting any repairs. Conduct all work from the mat. NEVER place nonconductive items on the mat.

Handle ESD-sensitive components properly. Do NOT handle ESD-sensitive component connection points, connector pins, leads or terminals.

Keep nonconductive materials away from work space. Static charges from nonconductive material may not be removed by grounding. Items of this nature should be kept well clear of the work space when handling ESD sensitive devices.

Follow correct procedures for static shielding bags. Store and transport all ESD sensitive devices in the shielding bags at all times except when being worked on. NEVER place more than one ESD sensitive device in a static shielding bag. NEVER place static generating nonconductive material inside a static shielding bag with an ESD sensitive device. Place any faulty ESD sensitive devices in a static shielding bag immediately after removal to prevent additional damage. Close and seal the bag to ensure that the shield is effective.

9.7 Repainting

Before repainting or touching up the ventilator, smooth out the area with fine sandpaper, and make sure it is free from any grease, corrosion, or dust. Remove the part to be painted or mask off the surrounding area to prevent over-spray or spills.

9.8 Nonconforming Parts and Return Authorization Numbers (RGA)

When investigating reported problems, identify the cause of the failure and repair or replace the component as necessary. Any failed, nonconforming parts, should be retained until the subject device has been successfully repaired. Following completion of the repair, any non-conforming parts should be returned to the manufacturer to allow failure analysis to be performed.

To arrange for return of non-conforming parts contact your local dealer. The dealer will request and receive a returns authorization number (RGA) from the manufacturer. Prior to

dispatch, non-conforming parts should be suitably packaged with a copy of any relevant service documentation enclosed. The return authorization number provided by the manufacturer should be clearly marked on all shipping documentation and on the exterior of the packaging.

9.9 Replacement Parts

To order correct parts, identify the ventilator's model and serial number. Then using the Parts List section of this manual (Section 10), identify the manufacturers part number for the item. Should you find the specific item is not available as a field replaceable unit (FRU) or that it is not stocked, order the next higher assembly level. Retain the part to be replaced until the replacement part is obtained, and compare the two for compatibility.

9.10 Post Repair and Testing

After successfully completing any ventilator repair, the following should be done prior to returning it to normal operation:

Visually verify that all pneumatic and electrical parts are properly connected and that all parts are properly installed. Verify that connections are secure and that parts are securely attached. Listen for any uncharacteristic sounds (pneumatic leaks, vibrations, grinding, etc). Be sure that the cooling fan and casters move freely. Check for any unusual odors.

Run the appropriate portions of the Inspiration ventilator performance verification procedure as indicated in the Performance Verification section of this manual (Section 7).

On completion of any ventilator repair, run any necessary calibration procedures.

9.11 Repair Documentation and Records

For convenience a Service Record, Warranty Claim, Complaint Form have been provided in this manual (see Section 13). Repairs or any work performed on the device should be recorded on these or similar documents.

A completed copy of this record must be communicated to eVent Medical or your local distributor.

9.12 Patient System and Accessories

For maintenance of the patient system and accessory items, consult the Inspiration ventilator system operator's instructions and refer to the applicable accessory manuals.

PROCEDURES

9.13 AC power - Removal/Installation

Remove the power cord retainer screw.

Disconnect the AC power cord from the AC inlet module.

9.14 Air/O2 Inlet Filter – Removal/Installation

Firmly grip the inlet assembly water trap and rotate counter-clockwise to remove.

Grip inlet filter and rotate counter-clockwise to remove. Replace as necessary or per the Preventative Maintenance schedule.

9.15 Air and oxygen water trap assemblies - Removal/Installation

Using a 2.5mm hex driver remove two screws on each water trap located on both sides of the DISS connectors.

Set aside both assemblies including the inlet filter bowls, filters and housings.

Using a 3mm hex driver remove the black connection block by removing the mounting screw located in the center of the block. Note the location of the O-rings and check valves that are installed in the connection block.

9.16 Internal Battery (DC) power – Removal/Installation

Remove air and O_2 inlet water traps.

Using a 2.5mm hex driver remove the small O_2 cell access door (if applicable,) and/or the rear battery compartment panel.

Slide the internal battery pack from the device and disconnect the battery wires. Note the orientation of the battery harness. A wiring diagram may be found on the inside of the battery compartment panel.

Set the battery pack aside. Replace as necessary or once every two years.

9.17 Oxygen Sensor – Removal/Installation

Using a 2.5mm hex driver remove the screws securing the O_2/battery panel to the lower housing.

Disconnect ground cable and set aside the O_2 cell / battery compartment panel.

Grip the O_2 cell and rotate counter-clockwise to disengage from the pneumatic assembly. Replace as necessary or once per year.

9.18 Ventilator Stand (Deluxe) – Removal/Installation

Ensure the brakes have been engaged to the casters on the base of the stand.

Ensure that all accessory items, tubing system, gas supply hoses and electrical source cables, have been removed from the ventilator.

While supporting the ventilator, loosen the 2 thumb screws securing the mounting plate to the head of the cart. Lift the ventilator head off and lay it on its side on a clean, padded, secure surface. Using a Philips head screw driver, remove the four screws securing the ventilator head to the mounting plate.

9.19 Front Housing – Removal/Installation (ST/LG only)

Ensure the ventilator is positioned on a secure flat surface. If the ventilator is secured to its stand ensure casters have the brakes engaged.

Using a 2.5mm hex driver remove two retaining screws from the alarm cone on the side of the top housing. Remove the alarm cone and set it aside (if applicable.)

Using a 4mm hex driver loosen but do not remove the four screws securing the two mounting rails to sides of the ventilator chassis.

Lift and tilt the top forward to access the main ribbon cable connecting the graphics module to the power board.

Disconnect the ribbon cable running from Controller/Mother PCB at the Power board end. Disconnect internal Ethernet cable (if installed) at the Motherboard end.

Disconnect the single spade ground cable from the front bezel.

Carefully lift off the top housing and place it on a grounded static dissipative mat or into a static shielding bag.

9.20 PU Front Housing – Removal/Installation (LS only)

Using a 2.5mm hex driver remove the four screws securing the PU front housing to the top housing.

Tilt the front housing forward on its hinges to access the graphics display module.

Disconnect the ribbon cable from the graphics motherboard.

Disconnect the Ethernet cable (if installed) from the mother board.

Disconnect the grounding wires from the front chassis.

Carefully partially close the front housing and lift it off its hinges and place it on a grounded static dissipative mat or into a static shielding bag.

9.21 Rotary Control Knob – Removal/Installation

Remove the top cover enclosure or PU Front housing and place it on static dissipative mat.

Disconnect the rotary control knob assembly cable from the Mother Board.

Disconnect the earth ground wire from the PU front panel hinge. (LS only)

Remove the Nose Cone assembly from the Front Panel by removing the attachment screws located on the inside of the Front Panel using a Phillips screwdriver.

Using a hex driver, loosen the set screw securing the knob to the rotary control knob device.

Using a nut driver or wrench, remove the nut and washer from the shaft of the rotary control knob.

Remove the rotary control knob from the top cover enclosure retaining all mounting hardware.

9.22 Mini Web Interface – Removal/Installation

Remove the top cover enclosure or PU Front housing and place it on static dissipative mat.

With attention to appropriate anti-static precautions and using hex driver remove the cap head screws securing the Mini Web Interface PCB to the Controller PCB/Mother Board.

Carefully unplug the Mini Web Interface PCB from the Controller PCB/Mother Board and place it into a static shielding bag.

Note:

Replacement MWI PCB's are provided with software versions current at the time of shipment. Up to date software files may need to be installed following the repair. Refer to the Software Installation section of this manual for detailed instructions.

9.23 Processor Board – Removal/Installation

Remove the top cover enclosure or PU Front housing and place it on static dissipative mat.

With attention to appropriate anti-static precautions and using hex driver remove four cap head screws securing the Processor Board to the Controller PCB/Mother Board.

Carefully unplug the Processor Board from the Controller PCB/Mother Board and place it into a static shielding bag.

Note:

Replacement Processor Boards are provided with software versions current at the time of shipment. Up to date software files may need to be installed following the repair. Refer to chapter Software Installation section of this manual for detailed instructions.

9.24 LCD – Removal/Installation

Remove top cover enclosure or PU Front housing and place it on static dissipative mat.

Disconnect the rotary encoder cable from the Controller PCB/ Mother Board.

Disconnect ribbon cable from the Lexan screen from the Controller PCB/ Mother Board.

LG Devices: Only

With attention to appropriate anti-static precautions and using 3.0mm hex driver remove four cap head screws securing the complete graphic module to the front housing.

Remove the complete graphic module and place it on a static dissipative mat with display facing upward.

Using 2.5mm hex driver remove four cap head screws securing the LCD to stand offs.

Carefully disconnect the backlight cable from the Controller PCB and the display ribbon cable from LCD.

LS Devices Only:

With attention to appropriate anti-static precautions and using a hex driver remove 4 x cap head screw securing the complete graphic module to the front housing.

Carefully disconnect the backlight cable from the Controller PCB, and the display ribbon cable from LCD.

Disconnect the touch screen ribbon cable from the Motherboard if applicable.

All Devices:

Place the LCD and remaining Graphic module components into a static shielding bag.

9.25 Graphic Board – Removal/Installation

Remove the top cover enclosure or PU Front housing and place it on static dissipative mat.

Remove Graphic module and LCD panel.

Using 2.5mm hex driver remove 4 x cap head screw securing the Graphic Board to the Controller PCB. Carefully unplug the Graphic Board from the Controller PCB and place in a static shielding bag.

9.26 Backlight Inverter – Removal/Installation

Remove the top cover enclosure or PU Front housing and place it on static dissipative mat.

Remove Graphic module and LCD panel.

Carefully disconnect the inverter cable(s) from the Inverter.

Using a 2.5mm hex driver remove two cap head screws securing the Inverter to the Controller PCB/graphic plate.

Place the Inverter in a static shielding bag.

9.27 DC Converter PCB – Removal/Installation (Non-Touch Screen LS only

Remove the PU Front housing and place it on static dissipative mat.

Remove Graphic module and LCD panel.

Using a 2.0mm hex driver remove two cap head screws securing the Power Converter PCB to the graphic plate.

Carefully disconnect the Power Converter PCB from the Graphic Board and place it in a static shielding bag.

9.28 Motherboard – Removal/Installation

Record the ventilator and compressor running hours, and any relevant error code information on service record prior to replacing the Controller PCB. This information is available on FabTest 11.

Remove the PU Front housing and place it on static dissipative mat.

Remove Graphic Board and LCD panel.

Remove the Mini Web Interface PCB.

Remove the Processor Board.

Remove the Graphic Board.

Using a 2.5mm hex driver remove four cap head screws securing the Controller PCB/Motherboard to the Graphic Plate.

Remove stand-offs and place the Controller PCB into a static shielding bag.

Note: It may be necessary to rebuild NVRAM when replacing the Motherboard. Refer to the Rebuilding NVRAM instructions in the SERVICE MODE/FABTEST section of this manual.

9.29 Lexan screen – Removal/Installation (LG only)

Note: For LS model ventilators do not replace the Lexan screen. Replace the PU complete front panel with Lexan screen installed.

Remove top cover enclosure and place on static dissipative mat.

Disconnect the Lexan screen ribbon cable from the Controller PCB/Mother Board.

Using a hex driver, loosen the set screw securing the knob to the rotary control knob device.

Remove the Phillips head screws securing the nose cone to the front housing.

Set the nose cone aside.

Starting in one corner, lift and peel the Lexan screen up and clear of the front housing .

Following removal ensure that front housing is cleaned and that the front lens is secure prior to installing new Lexan screen.

9.30 Compressor Module – Removal/Installation

Remove top cover enclosure and place on static dissipative mat.

The compressor is mounted using six compressor module screws.

Using 2.5mm hex driver remove the back two screws on each side and loosen but do not remove the front two.

Tilt the compressor module up and retighten the front two screws to hold to the compressor module in place.

Using flat bladed screw driver loosen the two hose clamps, then disconnect the two pneumatic hoses connecting the compressor to the pneumatic sensor block assembly.

Disconnect the AC wiring harness from the AC inlet module on the ventilator back panel.

Disconnect the power supply cable from the power board.

Disconnect the compressor cable from the power board and Sol. 3.

While supporting the compressor module, remove the two remaining screws securing the compressor platform to the bottom enclosure.

Remove the compressor platform and place it on the static dissipative mat or in a static shielding bag.

9.31 Rear Connection Panel- Removal/Installation

Remove the top cover enclosure and place on static dissipative mat.

Remove the Air and O_2 inlet assemblies

Using 2.5mm hex driver remove the back two screws on each side and loosen but do not remove the front two.

Tilt the compressor module up and retighten the front two screws to hold to the compressor module in place.

Disconnect the DC input cable from the Power board.

Disconnect the fan cable from the Power board.

Disconnect the grounding wire from the Power board.

Remove the four mounting screws that secure the panel to the back of the chassis.

Note:

The panel will still be connected to the ventilator by a grounding wire and four battery wires. Support the panel and do not pull the panel too far from the unit.

Disconnect the grounding wire from the side of the chassis.

Disconnect the four battery wires from the battery assembly.

Gently thread a grounding wire and battery wires out of the pneumatic block assembly.

Set the Rear Connection Panel aside.

9.32 Sensor board – Removal/Installation

Remove the top cover enclosure and place it on a static dissipative mat.

Using 2.5mm hex driver remove the back two screws on each side and loosen but do not remove the front two.

Tilt the compressor module up and retighten the front two screws to hold to the compressor module in place.

Disconnect the four battery wires from the battery assembly.

Disconnect the flat ribbon cable from the Power board at the Sensor board end.

Disconnect O_2 sensor interface cable from the Sensor board.

Using 2.5mm hex driver, remove the cap head screw securing the Sensor board to the pneumatic module (access through right side cut out).

Ease the Sensor board up out of the pneumatic module. Care should be taken not to flex the PCB excessively or damage the transducer connections

Place the Sensor board into a static shielding bag.

9.33 Power board – Removal/Installation

Remove top cover enclosure and place on static dissipative mat.

Remove the compressor module.

Disconnect the four battery wires from the battery assembly.

Disconnect flat ribbon cable from the Sensor board at the Power board end.

Disconnect the DC supply harness, cooling fan harness and grounding cable from the Power controller.

Disconnect connecting harnesses from air/O2 blender valves, Inspiration and exhalation proportional valves, nebulizer valve, Safety Valve, compressor system,

Loosen the screws securing the rear panel to the bottom enclosure. Ensure adequate space to disengage communications connectors from rear panel. If sufficient room is not available the rear panel should be removed. (See Rear Connection Panel- Removal/Installation.)

Using hex driver, remove the two cap head screws securing the Power board to the pneumatic module (access through right side cut out), and three screws securing the Power board standoffs to the lower housing.

Ease the Power board up out of the pneumatic module. Care should be taken not to flex the PCB excessively or damage the transducer connections.

Place Power board into a static shielding bag.

Note:

Replacement Power board's are provided with software versions current at the time of shipment. Up to date software files may need to be installed following the repair. Refer to chapter 12 of this manual for detailed instructions.

9.34 Blender Module – Removal/Installation

Remove the top cover enclosure.

Remove the compressor module.

Remove the Power board.

Disconnect the main pneumatic harness from the Air and Oxygen Blender Valves SV1 and SV2.

Using a hex driver remove the four cap head screws securing the blender system to the upper pneumatic chassis.

Lift out the blender module assembly.

9.35 Blender Valve – Removal Installation

Remove the top cover enclosure.

Remove the compressor module.

Disconnect the main pneumatic harness from the gas supply valves SV1 and SV2.

Using a 14mm open end wrench remove the nut securing the hub-magnet coils of valve (SV1/2) to the valve body.

Lift hub-magnet coils off and set them aside.

Note:

Two Torx head screws hold the valve base together and two Allen head screws hold the valve to the muffler block assembly. Do not loosen the torx head screws.

Remove the valves by removing two Allen head screws from each valve.

Caution:

While removing the Allen head screws from the valve assemblies it may be necessary to keep the rubber buffers, located under the muffler block, from turning. Excessive torque on the rubber buffers may damage them.

Note:

Observe the orientation of the valves as they are removed. Notice they are designed so high upstream pressure is directed to the top of the valve poppet. If the valve is installed incorrectly, the high pressure is applied to the bottom of the valve poppet and it may force the valve open creating a leak. The valve body must be oriented so the number stamped surface faces the front of the device.

Set the valve assemblies aside.

9.36 Blender Muffler Block - Removal/Installation

Remove the top cover enclosure.

Remove the compressor module.

Remove the Power board.

Remove the Blender Module.

Remove the Blender Valves.

Remove the muffler block by pulling up with firm but gentle pressure.

Observe the asymmetric tubes and impact filters located in the muffler block.

Note:

To prevent downstream contamination, maintain the orientation of the impact filters for reinstallation.

Reinstall the asymmetric tubes, impact filters and muffler block on the blender block assembly.

9.37 Blender Flow Sensor - Removal/Installation

Remove the top cover enclosure.

Remove the compressor module.

Remove the Blender Valve hub-magnet coils..

Remove four flow sensor retainer screws from the blender block and use firm but gentle pressure with a twisting motion to remove the flow sensor retainer from the block.

Identify the blender flow sensor element and note its orientation for reinstallation.

Reinstall the flow sensor retainer and sensor element in the blender block assembly.

Note:

Try to seat the flow sensor retainer completely, using firm but gentle pressure with a twisting motion, before installing the mounting screws. Use an alternating tightening pattern to tighten the mounting screws.

Reassemble the Blender Module assembly including SV1 and SV2 and set it aside.

9.38 Sensor Block 1 –Removal/Installation

Remove the top cover enclosure.

Remove the compressor module.

Remove the Sensor board.

Disconnect the Inspiratory Proportional Valve wiring harness.

Remove the four sensor block 1 mounting screws.

Lift out the sensor block and valve assembly.

9.39 Inspiratory Valve – Removal/Installation

Note the orientation of Inspiration valve prior to removal. The valve body must be oriented such that surface stamped with an arrow faces front of the device.

Remove the top cover enclosure.

Remove the compressor module.

Disconnect the Inspiratory Proportional Valve wiring harness.

Type 6022 Only:

Using a 14mm open end wrench remove the nut securing the hub-magnet of PV1 to the valve body, lift hub-magnet off and set aside.

Using a T20 torx driver remove the two screws securing PV1 to the sensor block 1.

Type 2833 Only:

Using a flat blade screw driver remove the two pan head screws securing the PV1 to sensor block 1.

Note: Pay special attention to the orientation of the valve. Do not disassemble the PV1 valve.

Observe the location of O-rings and mounting hardware for the solenoid.

9.40 Internal Flow Sensor – Removal/Installation

Remove the top cover enclosure.

Remove the compressor module.

Using 2.5mm hex driver remove the two cap head screws securing the internal flow sensor between sensor blocks 1 and 2.

Firmly grip flow sensor tab and slide the component up and out from between the blocks.

Note:

To prevent downstream contamination, maintain the orientation of the flow sensor for reinstallation

9.41 Sensor Block 2– Removal/Installation

Remove the top cover enclosure.

Remove the compressor module.

Disconnect the compressor unloading valve wiring harness.

Remove the two sensor block 2 mounting screws.

Lift out the sensor block assembly.

Note:

Pay special attention to the orientation of all o-rings and spacers mounted between the blocks and ensure that none are lost.

9.42 Safety Valve Block – Removal/Installation

Remove the top cover enclosure.

Remove the compressor platform.

Using hex driver remove the four screws securing the security block to sensor block 2.

Set security block on a secure clean surface for further disassembly.

9.43 Over Pressure Valve – Removal/Installation

Remove the top cover enclosure.

Remove the compressor platform.

Remove the Safety Valve Block.

Pull the over pressure valve cartridge out from the security block.

9.44 Safety Valve – Removal/Installation

Remove the top cover enclosure.

Remove the compressor platform.

Remove the Safety Valve Block.

Lift top block from the Safety Valve Block.

Manually unscrew the security valve plunger from the actuator. Set the plunger and top diaphragm aside.

Using a hex driver remove the two cap head screw securing the Safety Valve to the top block.

9.45 Nebulizer Valve – Removal/Installation

Remove the top cover enclosure.

Disconnect nebulizer harness from the terminals of the nebulizer valve.

Using a 14mm open end wrench remove the nut securing the hub-magnet of SV4 to the valve body. Lift hub-magnet off and set aside.

Using a T8 torx driver remove the two screws securing SV4 to the front block.

9.46 Front Block – Removal/Installation

Remove the top cover enclosure.

Remove the nebulizer valve.

Using a hex driver, remove the two cap head screws securing the front pneumatic block to the upper pneumatic chassis.

9.47 Exhalation Valve – Removal/Installation

Remove the top cover enclosure.

Disconnect the exhalation valve at the Power board.

Using a 2.5mm hex driver remove the two cap head screws securing the exhalation cover locking ring in position. Set locking ring components aside.

Using a 2.5mm hex driver remove the two cap head screws securing the exhalation valve to the bottom pneumatic chassis. Withdraw exhalation valve from the pneumatic chassis and set aside.

9.48 Complete Pneumatic Chassis – Removal/Installation

Remove the top cover assembly.

Remove the compressor platform.

Remove the Gas Inlet Assemblies.

Remove the Rear Panel.

Remove the screws securing the battery/O_2 sensor compartment cover and disconnect DC harness from the battery terminals.

Remove the battery assembly.

Remove the two screws securing the pneumatic chassis to either side of the bottom housing.

Carefully lift the complete pneumatic chassis out of the bottom housing and place on a secure surface.

Section

10

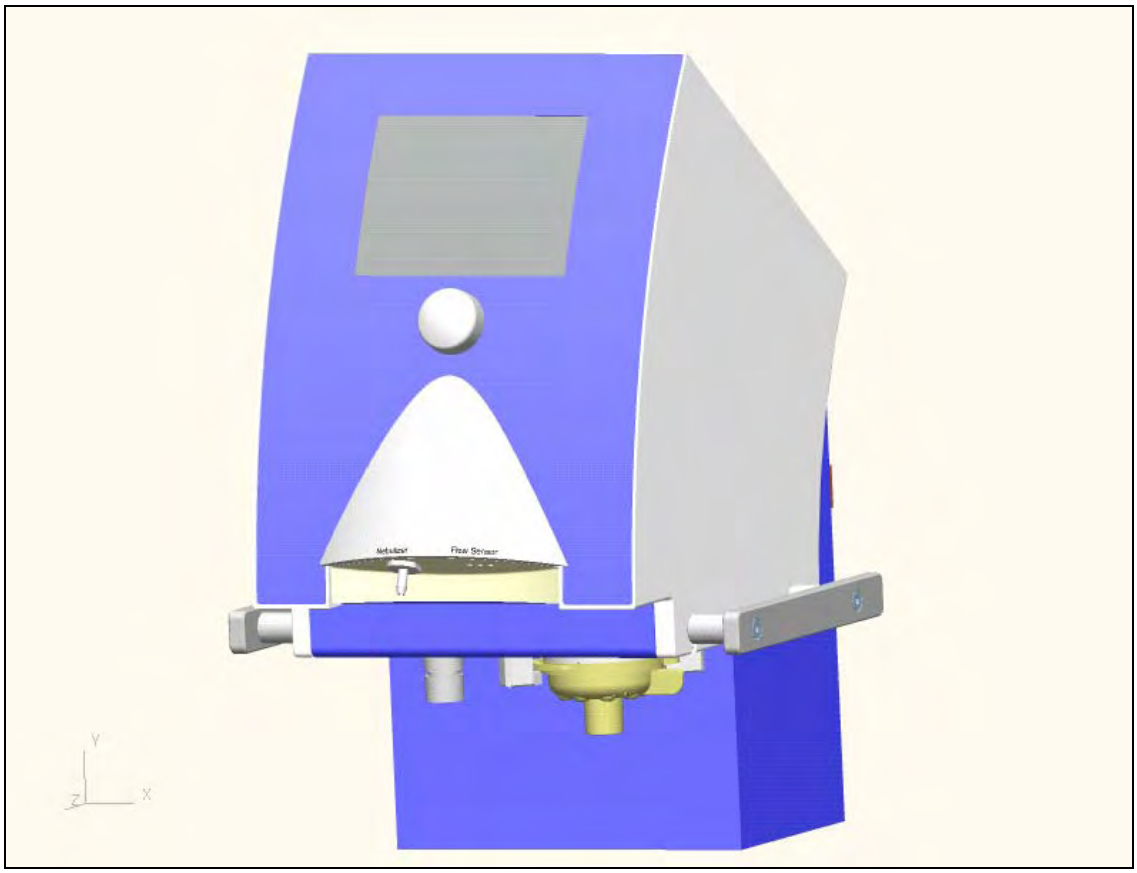
PARTS LIST

10.1 Introduction

This section begins by showing the entire ventilator system, including accessory items. Subsequent figures show ventilator subassemblies and their component parts. A numeric parts index is also included at the back of this section, along with a Field Replaceable Unit (FRU) index, to assist in the identification of the correct components.

10.2 Ventilator Assembly – MODEL F7300000-XX – INSPIRATION LS

Item No	Part No.	Description
01	F7300000-DE	Inspiration Ventilator, German
	F7300000-ES	Inspiration Ventilator, Spanish
	F7300000-FR	Inspiration Ventilator, French
	F7300000-GB	Inspiration Ventilator, English (UK)
	F7300000-IN	Inspiration Ventilator, English (IN)
	F7300000-IT	Inspiration Ventilator, Italian
	F7300000-JP	Inspiration Ventilator, Japanese
	F7300000-PL	Inspiration Ventilator, Polish
	F7300000-PT	Inspiration Ventilator, Portuguese
	F7300000-RU	Inspiration Ventilator, Russian
	F7300000-US	Inspiration Ventilator, US



10.3 Ventilator Assembly – MODEL F7200000 – INSPIRATION ST

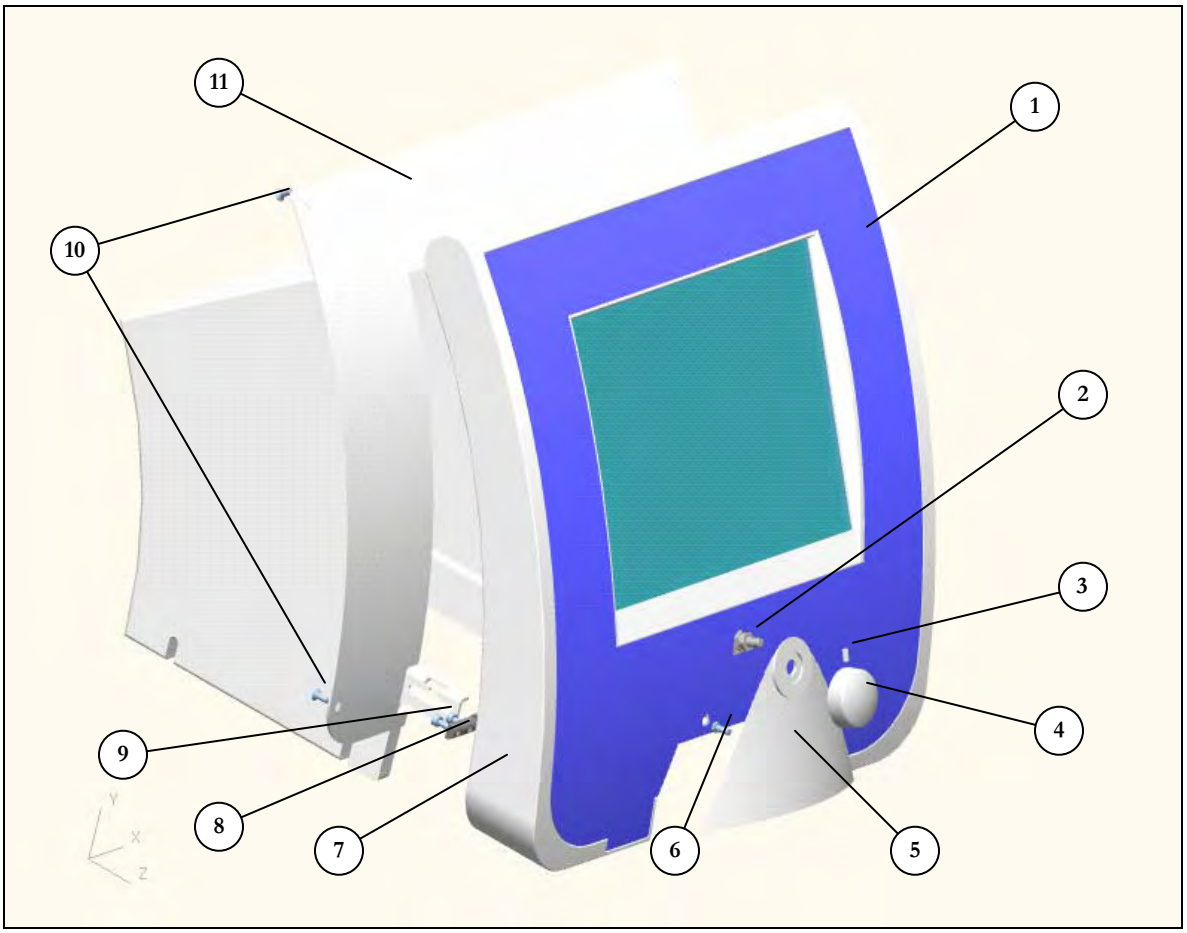
Item No	Part No.	Description
01	F7200000-DE	Inspiration Ventilator, German
	F7200000-ES	Inspiration Ventilator, Spanish
	F7200000-FR	Inspiration Ventilator, French
	F7200000-GB	Inspiration Ventilator, English (UK)
	F7200000-IN	Inspiration Ventilator, English (IN)
	F7200000-JP	Inspiration Ventilator, Japanese
	F7200000-IT	Inspiration Ventilator, Italian
	F7200000-PL	Inspiration Ventilator, Polish
	F7200000-PT	Inspiration Ventilator, Portuguese
	F7200000-RU	Inspiration Ventilator, Russian
	F7200000-US	Inspiration Ventilator, US

10.4 Ventilator Accessories		
Item No	**Part No.**	**Description**
Not Shown	F910203-PKG	EZ Flow Sensor Adult/Pedi, SPU, (10 Pack)
Not Shown	F-910204-PKG	EZ Flow Sensor, Infant, SPU, (10 Pack)
Not Shown	F910260	Tubing, EZ Flow Sensor, SPU, (10 Pack)
Not Shown	F710213	Exhalation Diaphragm
Not Shown	F710213-PKG	Exhalation Diaphragm, (10 Pack)
Not Shown	F710214	Exhalation Cover
Not Shown	F710216	DISS Adapter, Air
Not Shown	F710215	DISS Adapter, Oxygen
Not Shown	F910037	DISS Hose Assembly, Air
Not Shown	F910038	DISS Hose Assembly, Oxygen
Not Shown	F910217	NIST Hose Assembly, Air
Not Shown	F910218	NIST Hose Assembly, Oxygen
Not Shown	F910219	High Pressure Hose, Italian, Air
Not Shown	F910220	High Pressure Hose, Italian, Oxygen
Not Shown	F910085	Software Download Cable
Not Shown	F710102	Inspiration Ventilator Cart, Standard
Not Shown	F710513	Inspiration Ventilator Cart, Transport
Not Shown	F730744	Inspiration Ventilator Cart, Transport, Grey
Not Shown	F710522	Inspiration Ventilator Cart, Deluxe
Not Shown	F710562	Inspiration Ventilator Cart, Deluxe, Grey
Not Shown	F710519	Cylinder Mounts, Dual US E Cylinder
Not Shown	F710523	Cylinder Mounts, Dual Euro Cylinder

10.5 Front Housing Module – INSPIRATION LS, GREY

Item No	Part No.	Description
1	F730721-IN	12.1" Lexan screen, Grey, English
	F730721-DE	12.1" Lexan screen Grey, German
	F730721-ES	12.1" Lexan screen Grey, Spanish
	F730721-FR	12.1" Lexan screen Grey, French
	F730721-IT	12.1" Lexan screen Grey, Italian
	F730721-JP	12.1" Lexan screen Grey, Japanese
	F730721-PL	12.1" Lexan screen Grey, Polish
	F730721-PT	12.1" Lexan screen Grey, Portuguese
	F730721-RU	12.1" Lexan screen Grey, Russian
2	F730716	Encoder Knob LS, Grey
3	F730710	Nose cone grey, LS
Not Shown	F910005	Encoder switch
4	F730727	Encoder Knob Ring

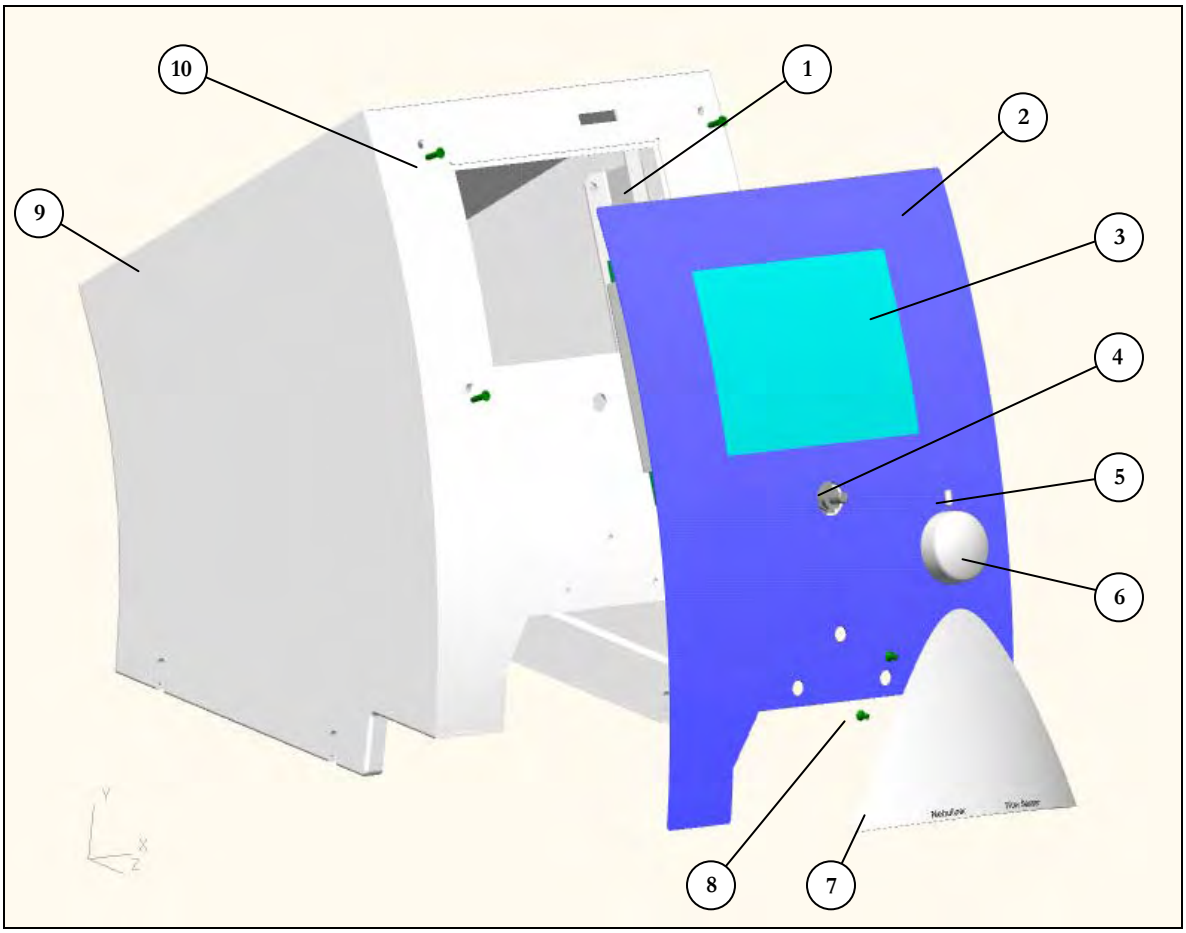
Not Shown	F930148 F930149 F930150 F930151 F930152 F930153 F930154 F930155 F930156 F930157	Nose Cone, English. FRU Nose Cone, Spanish. FRU Nose Cone, Russian. FRU Nose Cone, Japanese. FRU Nose Cone, Polish. FRU Nose Cone, German. FRU Nose Cone, French. FRU Nose Cone, Italian. FRU Nose Cone, Portuguese. FRU Nose Cone, Chinese. FRU
Not Shown	F730715	Encoder, 6.5" cable
5	F930137-XX	Front Housing Grey PU Complete, FRU XX: Language version of the applied lexan screen
5 w/Touch Screen	F930160-XX	Touch Screen Front Housing, Grey PU XX: Language version of the applied lexan screen
6	F730717	PU Housing, Metallic Grey
6 w/ Touch Screen	F730730	PU Housing, TS
Not Shown	F730221	Hinge, PU
Not Shown	F810016	Hex Socket Cap Head Screw, M4X12
Not Shown	F810017	Hex Socket Countersunk Screw M3 x 12
Not Shown	F730202	Top Housing, Coated, 12.1"
Not Shown	F930003	Earth Cable, 12.1", Front
Not Shown	F730732	Encoder Earth Cable



10.6 Front Housing Module – INSPIRATION LS

Item No	Part No.	Description
1	F730515-DE	Lexan Screen, 12.1", German
	F730515-ES	Lexan Screen, 12.1", Spanish
	F730515-FR	Lexan Screen, 12.1", French
	F730515-GB	Lexan Screen, 12.1", English
	F730515-IT	Lexan Screen, 12.1", Italian
	F730515-JP	Lexan Screen, 12.1", Japanese
	F730515-PL	Lexan Screen, 12.1", Polish
	F730515-PT	Lexan Screen, 12.1", Portuguese
	F730515-RU	Lexan Screen, 12.1", Russian
2	F910005	Encoder switch
3	F810011	Threaded Pin, M4X8
4	F730210	Push and turn knob

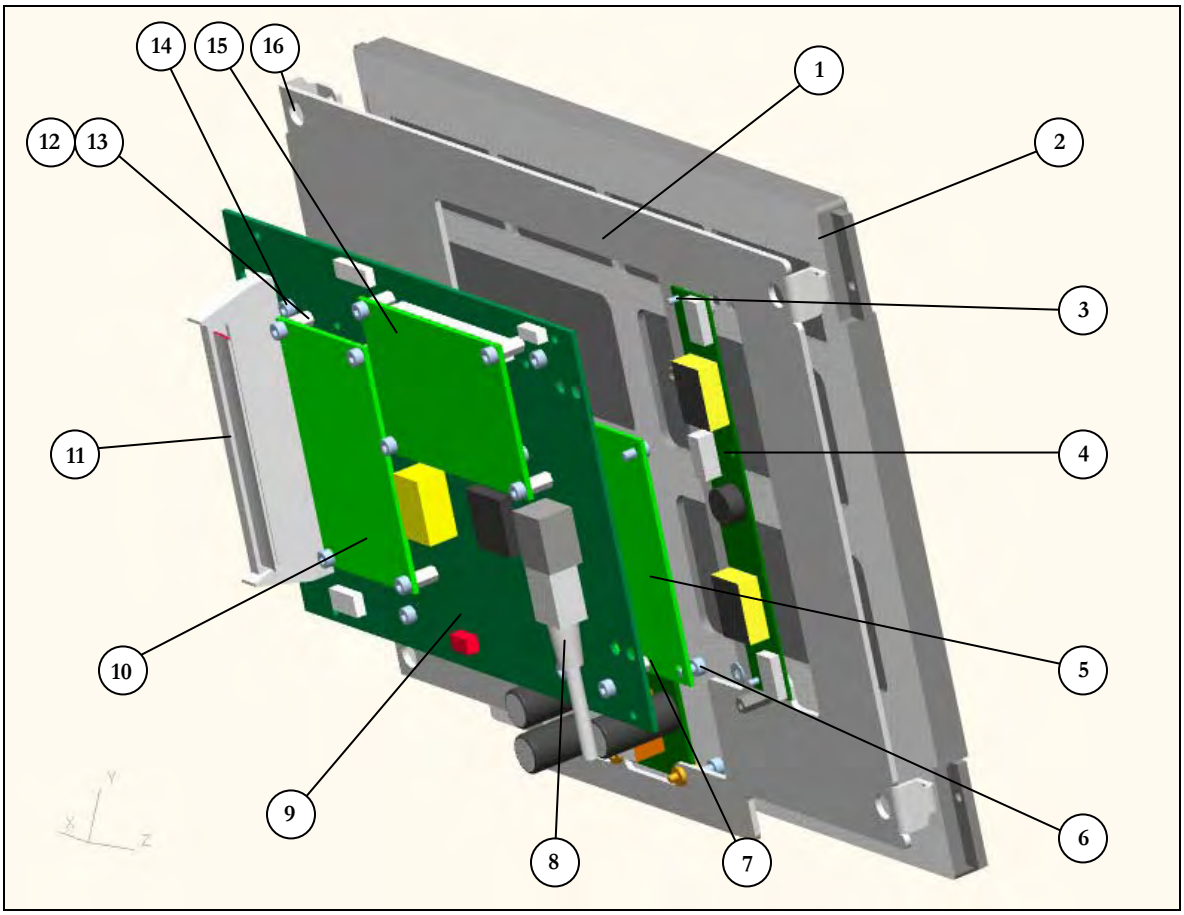
5	F730203-DE F730203-ES F730203-FR F730203-UK F730203-IT F730203-JP F730203-PL F730203-PT F730203-RU	Nose Cone, German Nose Cone, Spanish Nose Cone, French Nose Cone, English Nose Cone, Italian Nose Cone, Japanese Nose Cone, Polish Nose Cone, Portuguese Nose Cone, Russian
6	F830001	Phillips screw, K40X10
7	F910244-XX	Front Housing PU Complete (includes ref 1)
7 w/ Touch Screen	F930168	Front Housing PU Complete, TS (Includes ref 1)
8	F730221	Hinge, PU
9	F810016	Hex socket cap head screw, M4X12
10	F810017	Hex Socket Countersunk Screw M3 x 12
11	F730202	Top Housing, coated, 12.1"
Not Shown	F930003	Earth Cable, 12.1" Front



10.7 Front Housing Module – INSPIRATION ST

Item No	Part No.	Description
1	F720701	Bracket, Graphic Module
2	F720515-DE	Lexan Screen, 6.4", German
	F720515-ES	Lexan Screen, 6.4", Spanish
	F720515-FR	Lexan Screen, 6.4", French
	F720515-UK	Lexan Screen, 6.4:", English
	F720515-IT	Lexan Screen, 6.4", Italian
	F720515-JP	Lexan Screen, 6.4", Japanese
	F720515-PL	Lexan Screen, 6.4", Polish
	F720515-PT	Lexan Screen, 6.4", Portuguese
	F720515-RU	Lexan Screen, 6.4", Russian
3	F720211	Display Glass, 6.4"
4	F910005	Encoder switch
5	F810011	Threaded Pin, M4X8

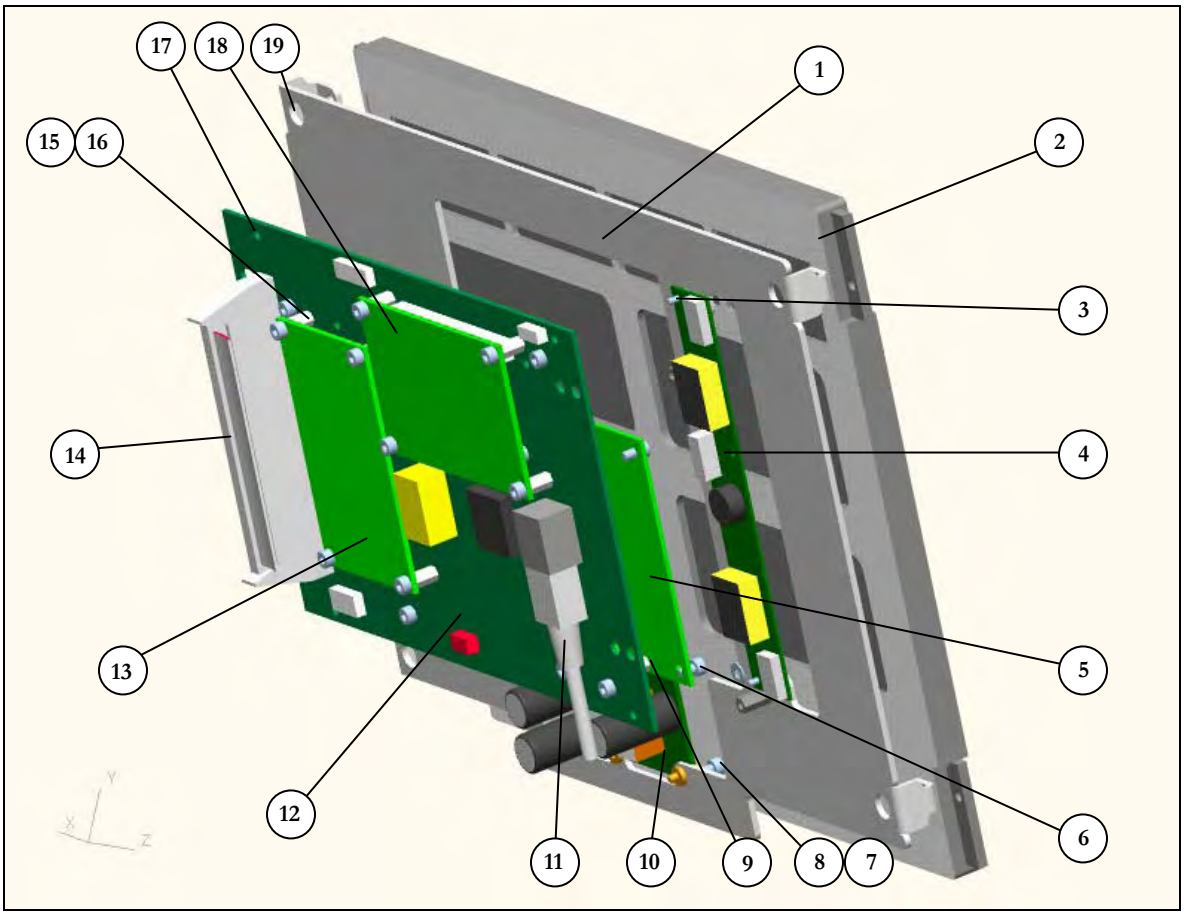
6	F710210	Push and Turn knob
7	F710203-DE F710203-ES F710203-FR F710203-UK F710203-IT F710203-JP F710203-PL F710203-PT F710203-RU	Nose Cone, German Nose Cone, Spanish Nose Cone, French Nose Cone, English Nose Cone, Italian Nose Cone, Japanese Nose Cone, Polish Nose Cone, Portuguese Nose Cone, Russian
8	F810132	Self tapped screw, Plastite No. 6, ¼ pan head
9	F910241	Top Housing 6.4" FRU (includes Ref 01,02,03)
10	F810082	Hex Socket Countersunk screw, M3X12



10.8 Graphic Module – INSPIRATION LS with Touch Screen

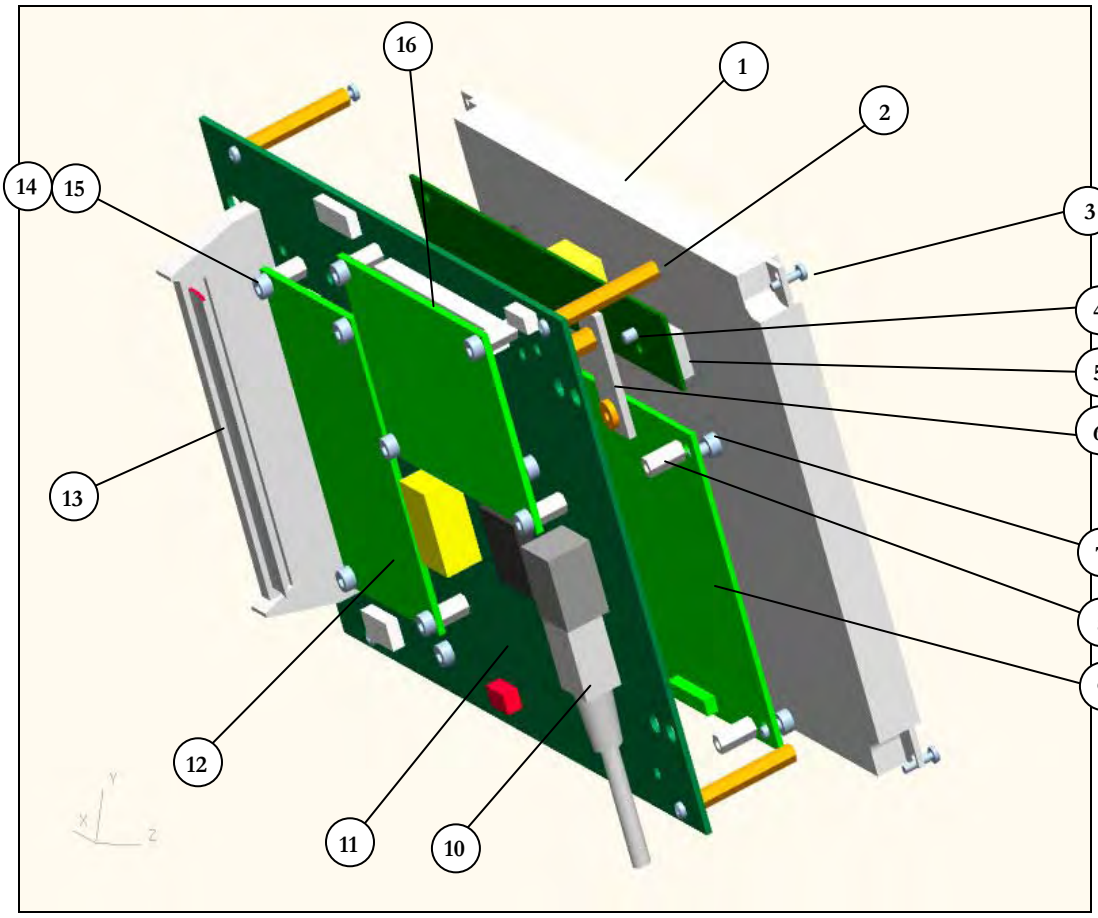
Item No	Part No	Description
1	F730701	Connection Plate, 12.1”
2	F930106	LCD,12.1”
3	F830005	Hex Socket Cap Head screw, M2X5
4	F930104	Inverter, 12.1” LCD
5	F930111	12.1” Graphic Board
6	F810075	Hex Socket Cap head screw, M3X5
7	F820016	Distance Pin, M3 (10mm/5mm)
8	F920062	Ethernet Cable
9	F720510	Motherboard
10	F910015	Processor Board
11	F920060	Controller Cable
12	F810088	Hex Socket Cap Head screw, M3X6
13	F810087	Distance Bolt M3 (7mm/5mm)

14	F810075	Hex Socket Cap Head screw, M3X5
15	F910089	Mini Web Interface FRU
16	F820021	Hex Socket Cap Head Screw M3x10, Stainless Steel
Not Shown	F930734	Graphic Cable
Not Shown	F930070	Inverter Cable, 12.1" LCD unit
Not Shown	F930105	Backlight Assembly, ST
Not Shown	F730735	Display Adapter PCB



10.9 Graphic Module – INSPIRATION LS		
Item No	**Part No**	**Description**
1	F730701	Connection Plate
2	F930106	LCD, 12.1”
3	F830005	Hex Socket Cap Head screw, M2X5
4	F930104	Inverter, 12.1” LCD
5	F930111	12.1” Graphic Board
6	F810075	Hex Socket Cap Head screw, M3X5
7	F830006	Hex Socket Fillister Head screw, M3X8
8	F830007	Bolt Spacer, Rounds, 3.1X3
9	F820016	Distance Pin, M3 (10mm/5mm)
10	F730513	DC Converter PCB, LS only
11	F920062	Ethernet Cable
12	F720510	Motherboard
13	F910015	Processor Board

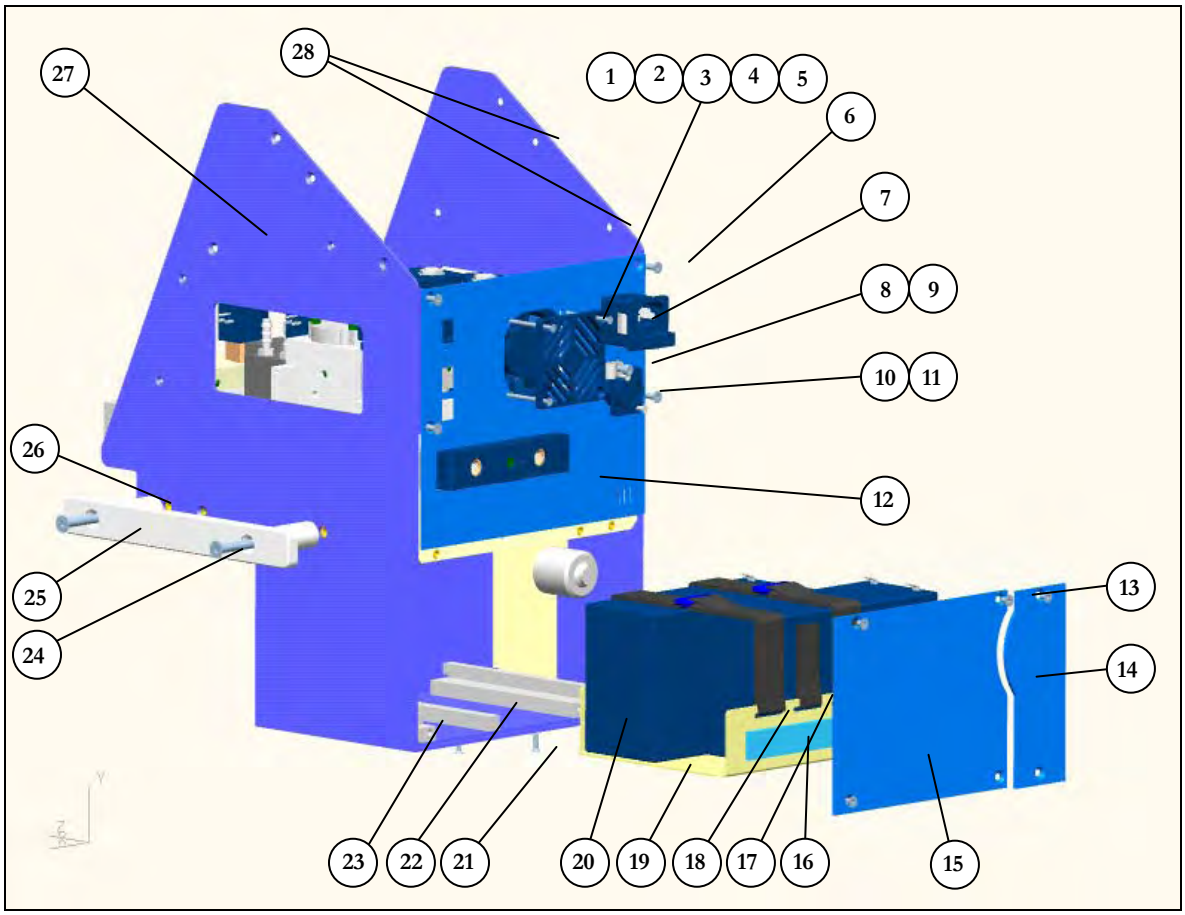
14	F920060	Controller Cable
15	F810088	Hex Socket Cap Head screw, M3X6
16	F810087	Distance Bolt M3 (7mm/5mm)
17	F810075	Hex Socket Cap Head screw, M3X5
18	F910089	Mini Web Interface FRU
19	F820021	Hex Socket Cap Head Screw M3x10, Stainless Steel
Not Shown	F930107	LCD Cable, 12.1"
Not Shown	F930070	Inverter Cable, 12.1" LCG
Not Shown	F930105	Backlight Assembly, ST
Not Shown	F820024	EMC Ferrite Bead
Not Shown	F820025	Clip, EMC Ferrite Bead



10.10 Graphic Module – INSPIRATION ST

Item No	Part No	Description
1	F920001	6.4" VGA TFT Display
2	F820015	Distance Pin, M2 (30mm/4mm)
3	F820018	Hex Socket Cap Head screw, M2X8
4	F810088	Hex Socket Cap Head screw, M3X6
5	F920104	Inverter, 6.4" LCD
6	F720703	Print support sheet, metal
7	F810075	Hex Socket Cap Head screw, M3X5
8	F820016	Distance Pin, M3 (10mm/5mm)
9	F920124	6.4" Graphic Board
10	F920062	Ethernet Cable
11	F720510	Motherboard
12	F910015	Processor Board
13	F920060	Controller Cable

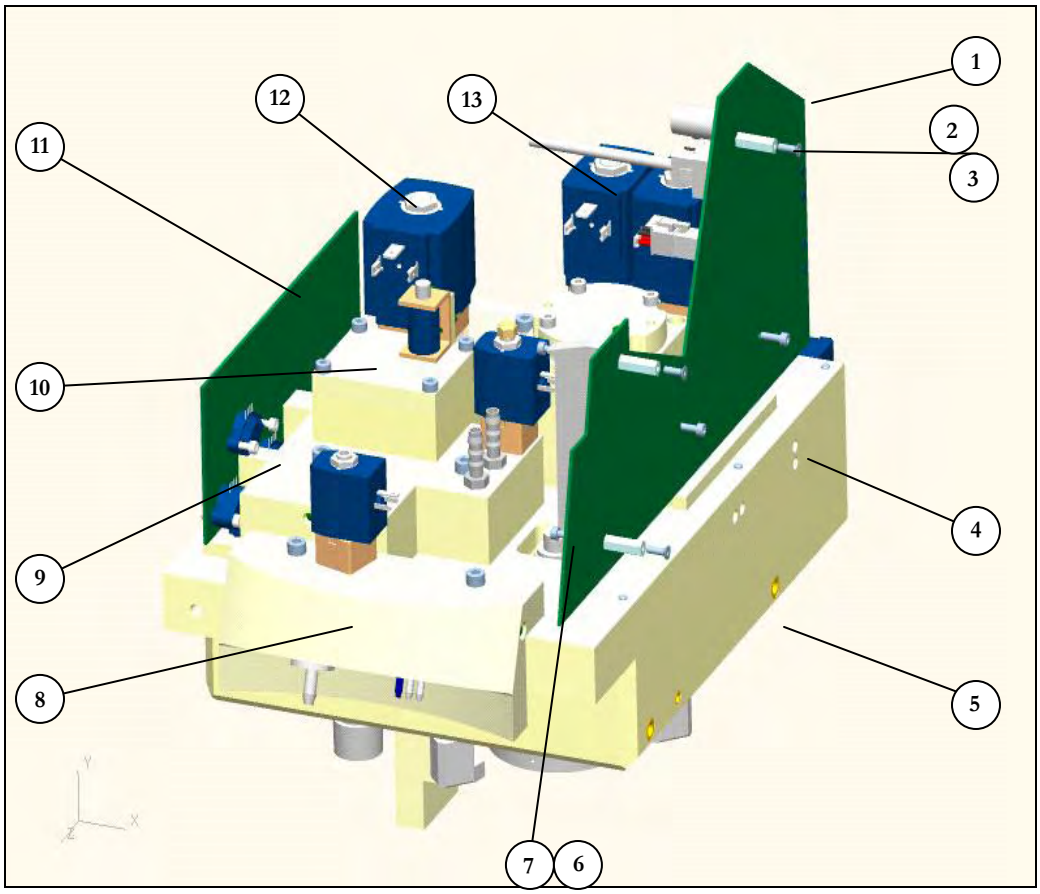
14	F810088	Hex Socket Cap Head screw, M3X6
15	F810087	Distance Pin, M3 (7mm/5mm)
16	F910089	Mini Web Interface FRU
Not Shown	F920069	Cable, 6.4" LCD
Not Shown	F920070	Inverter Cable, 6.4" LCD
Not Shown	F920105	Backlight Assembly, ST
Not Shown	F820024	EMC Ferrite Bead
Not Shown	F820025	Clip, EMC Ferrite Bead
Not Shown	F810016	Hex Socket Cap Head screw, M4X12



10.11 Lower Housing – INSPIRATION LS / ST

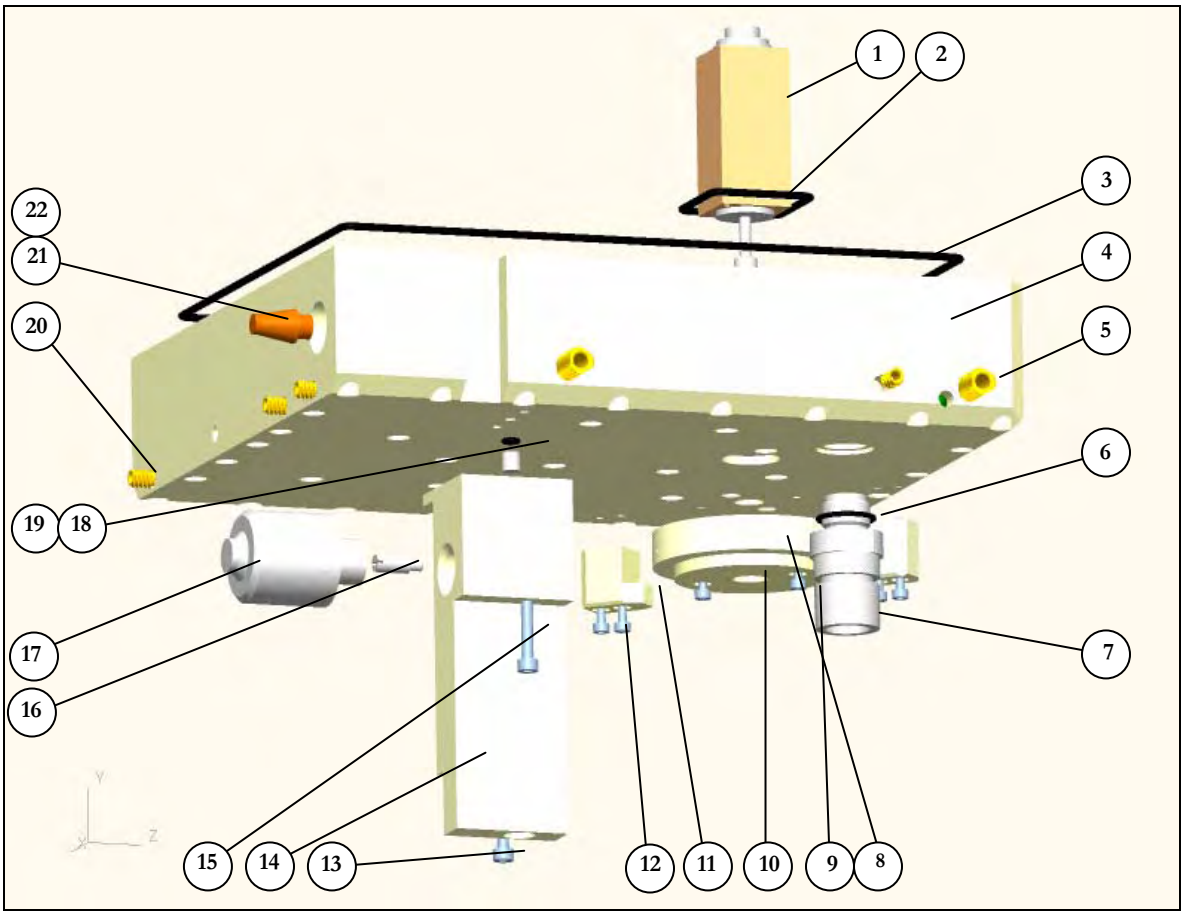
Item No	Part No	Description
1	F910252	Cooling fan, FRU
2	F910007	Cooling fan filter
3	F810015	Hex Socket Countersunk screw, M3x16
4	F810018	Screw nut, M3
5	F810019	Serrated Lock Washer, M3
6	F810017	Hex Socket Countersunk screw, M3X12
7	F910008	Power Entry Module
8	F910009 F810217	P-Clip, 6mm Power Cord retainer, P-Clip, US / JP
9	F810016	Hex Socket Cap Head screw, M4X12
10	F810001	Chassis connector, female
11	F810017	Screw, DC connector
Not Shown	F730713	Back Plate, Grey

12	F720204	Back Plate, 7A
Not Shown	F730714	Battery Cover, Grey
13	F810216	Hex Socket Countersunk screw, M3X12
14	F720207	O_2 Sensor Cover
15	F720206	Battery & O_2 Sensor Cover
16	F820006	Damping Mat
17	F820005	Short Belt
18	F820004	Long Belt
19	F720241	Batteries Holder
20	F910251	Internal Battery Pack, FRU
21	F810017	Hex Socket Countersunk screw, M3X12
22	F720205	Battery Support
23	F720217	Guide Rail
24	F810004	Hex Socket Countersunk Screw M6x60
25	F710209	Side Rail, Handle
26	F710208	Spacer, Handle
Not Shown	F730711	Bottom Housing, Grey
27	F720201	Bottom case 7A
28	F810216	Hex Socket Countersunk screw, M4X8
Not Shown	F910214	Fan Filter Element (5 pack)
Not Shown	F710222	ET cuff
Not Shown	F810017	Hex Socket Countersunk screw, M3X12
Not Shown	F910210	Label, Do not obstruct
Not Shown	F910211	Label, to/from Patient (JP only)
Not Shown	F920071	Earth Cable, 10cm (Filter/L Chassis
Not Shown	F920072	Earth Cable, 18cm (Power PCB)
Not Shown	F920073	Earth Cable, 35cm (O_2 Cover)
Not Shown	F920074	Earth Cover, 50cm (Front Chassis)
Not Shown	F730732	Encoder Earth Cable
Not Shown	F810135	Fuse set of 2 x 3.15AT/250V



10.12 Ventilator Pneumatic Chassis

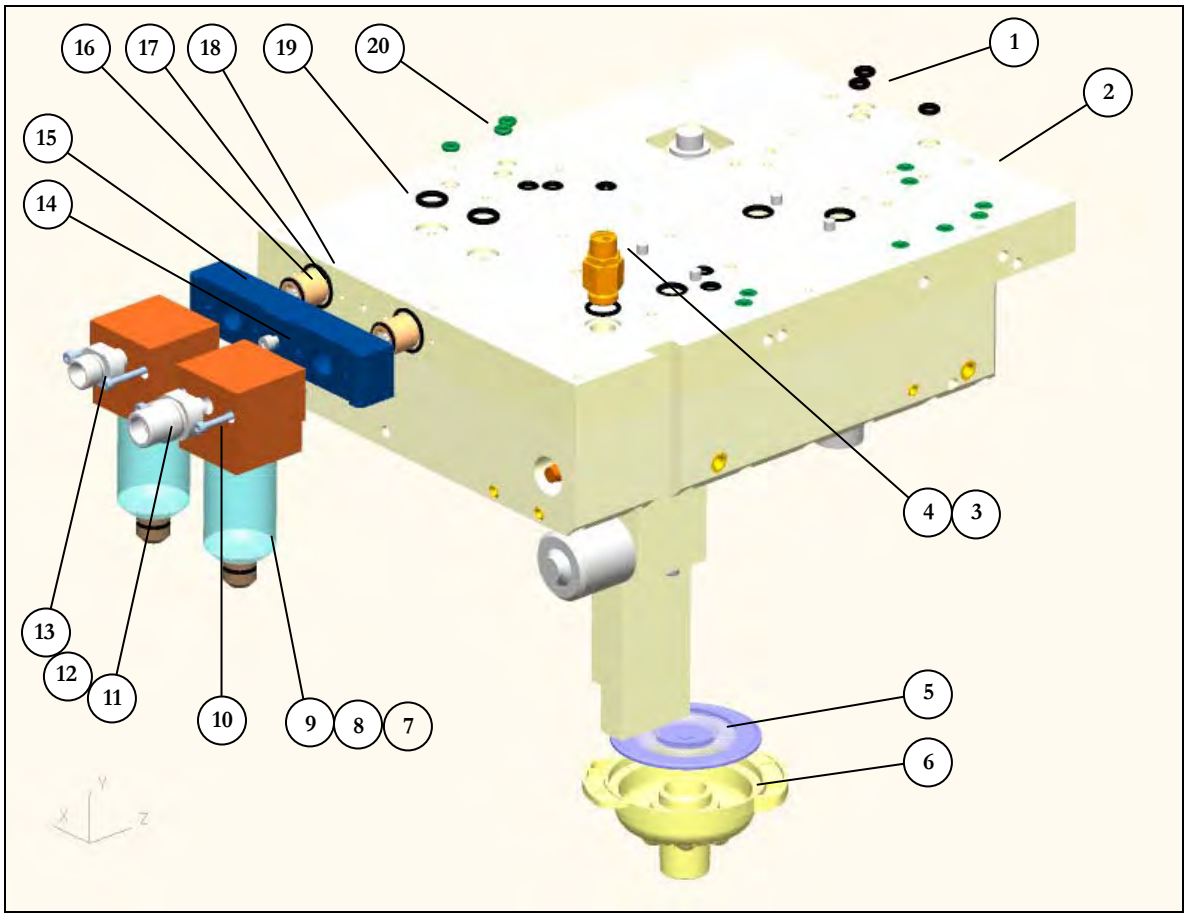
Item No.	Part No.	Description
1	F720511	Power Board
2	F820022	Hex Socket Countersunk screw, M3X10
3	F820019	Distance Bolt, M3X18mm, Polyamide
4	Reference Only	Upper Block Assembly
5	Reference Only	Lower Block Assembly
6	F820021	Hex Socket Cap Head screw, M3X10
7	F820020	Insulating washer, M3
8	Reference Only	Front Block Assembly
9	Reference Only	Sensor Block 2 Assembly
10	Reference Only	Safety Valve Block Assembly
11	F710512	Sensor board
12	Reference Only	Sensor Block 1 Assembly
13	Reference Only	Blender Block Assembly



10.13 Pneumatic Lower Module

Item No.	Part No.	Description
1	F910310	PV2 Exhalation Valve
2	F910246	O-ring, EValve Enclosure, FRU
3	F910245	O-ring, Tank Main, FRU
4	F910242	Pneumatic Bottom Block, FRU
5	F820010	Threaded Insert, M6
6	F810042	O-ring, FPM 75.5/VA75, 1.78X17.17
7	F710305	Inpsiratory Port
8	F710309	Locking Ring, Outer
9	F810012	Hex Socket Cap Head screw, M3X10
10	F710310	Locking Ring, Inner
11	F710311	Ring Holder
12	F810041	Hex Socket Cap Head screw, M3X25
13	F810016	Hex Socket Cap Head screw, M4X12

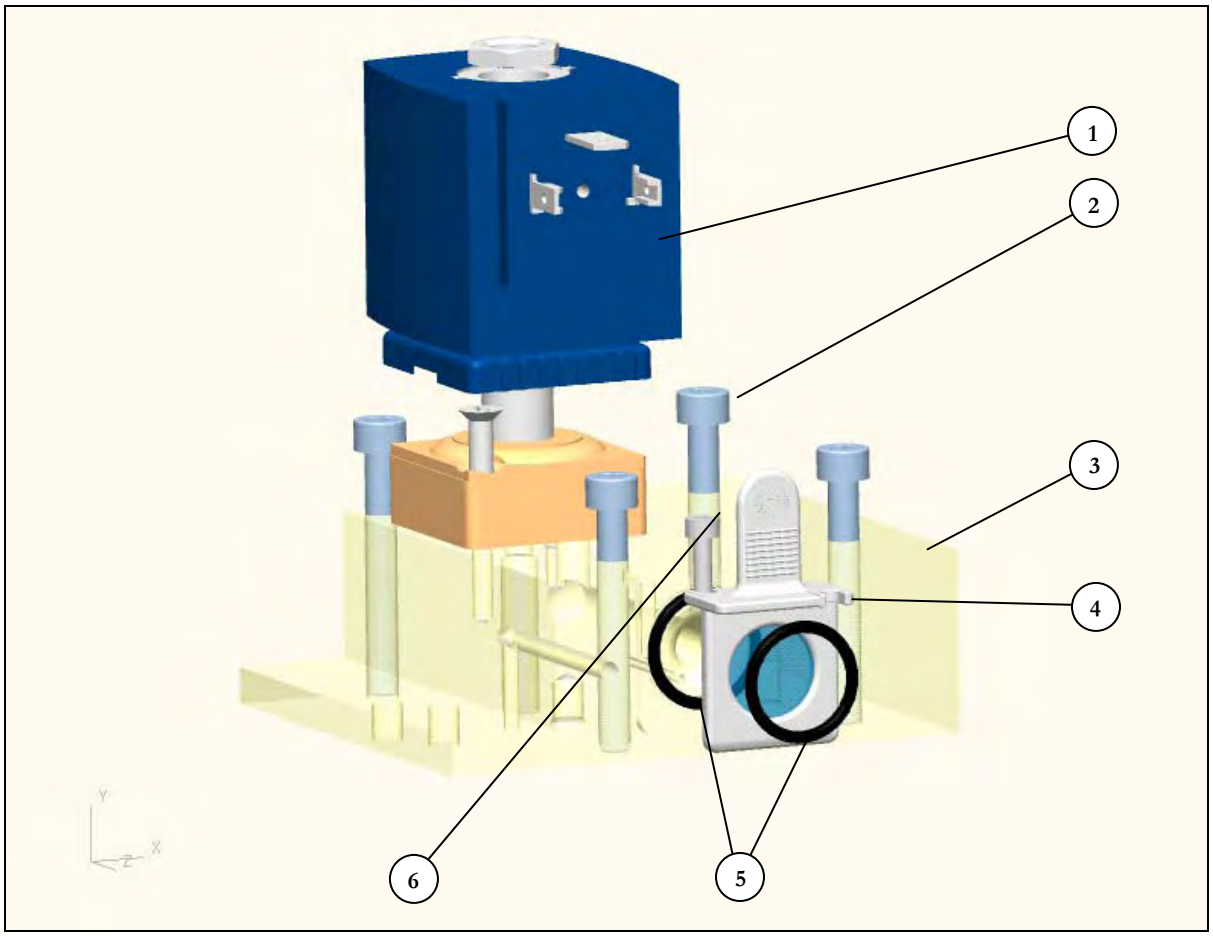
14	F910243	O_2 Sensor block, LS & ST, FRU
15	F820009	Hex Socket Cap Head screw, M4X50
16	F710308	Oxygen Cell Tube
17	F910028	Galvanic Oxygen Sensor
18	F910027	Restrictor, O_2 Measurement
19	F810063	O-ring, FPM 75.5/VA75, 1.78X2.9
20	F810203	Threaded Insert, M4
21	F810044	Inlet Filter, Compressor
22	F920100	Blanking Cap, G 1/8"



10.14 Pneumatic Upper Block

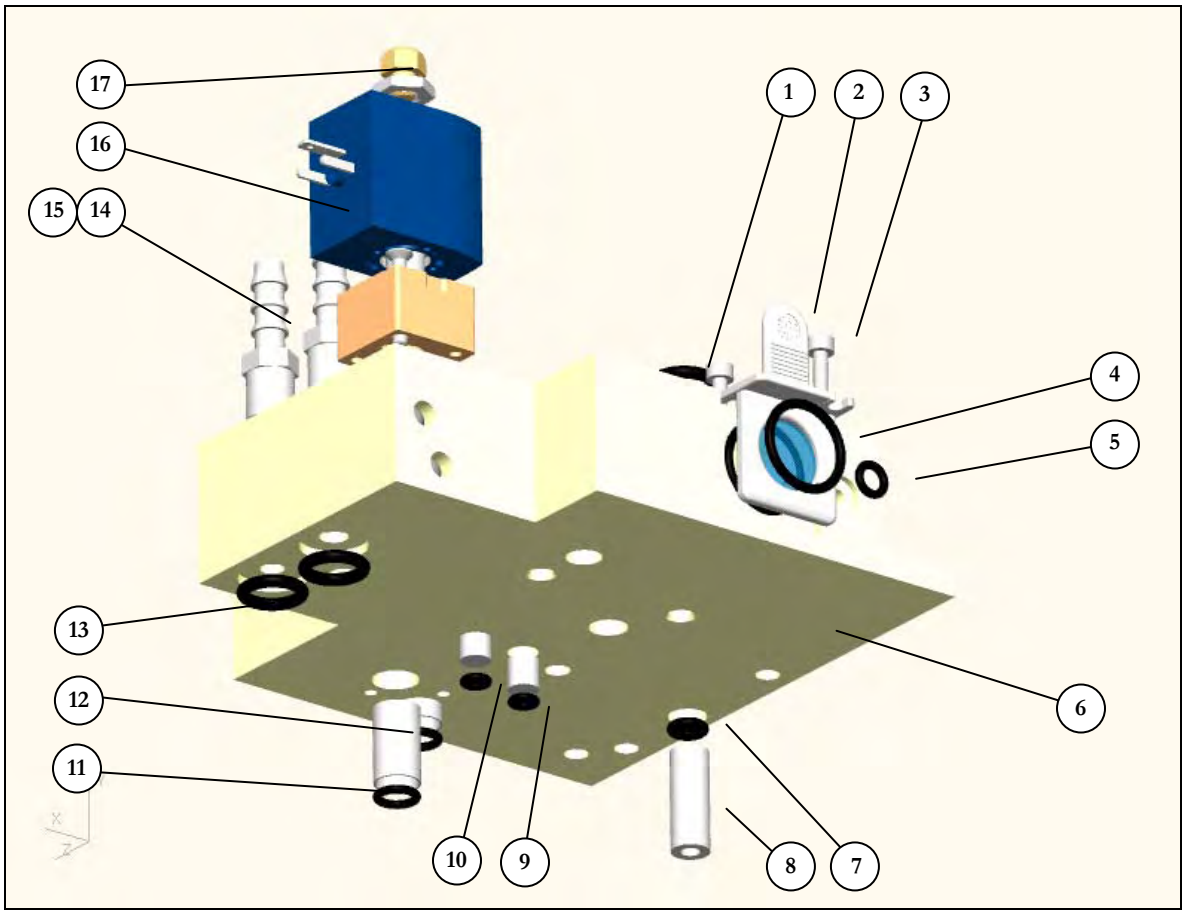
Item No.	Part No.	Description
1	F810031	O-ring, FPM 75.5/VA75, 2.62X4.42
2	F710302	Pneumatic Top Block
3	F910201	Tank over pressure valve
4	F810204	O-ring, FPM 75.5/VA75, 2X12
5	F710213	Membrane, eVent style
6	F710214	Evalve Cover, eVent style
7	F910016	Compressed Air filter/water trap
8	F910205	Filter element
9	F910216	Bowl, Water Trap
10	F810008	Hex Socket Cap Head screw, M3X60
11	F710216	DISS Air Connector, Male
12	F810007	O-ring, FPM 75.5/VA75, 1.5X10

13	F710215	DISS O_2 Connector, Male
14	F810059	Hex Socket Cap Head screw, M4X25
15	F710313	Gas Inlet Block
16	F810042	O-ring, FPM 75.5/VA75, 1.5X13
17	F810061	Inlet check valve, Air/O_2, 7.5 mbar
18	F810037	O-ring, FPM 75.5/VA75, 1.5X13
19	F810032	O-ring, FPM 75.5/VA75, 2.62X9.19
20	F810085	O-ring, FPM 75.5/VA75, 2.4X 3.3



10.15 Sensor Block 1

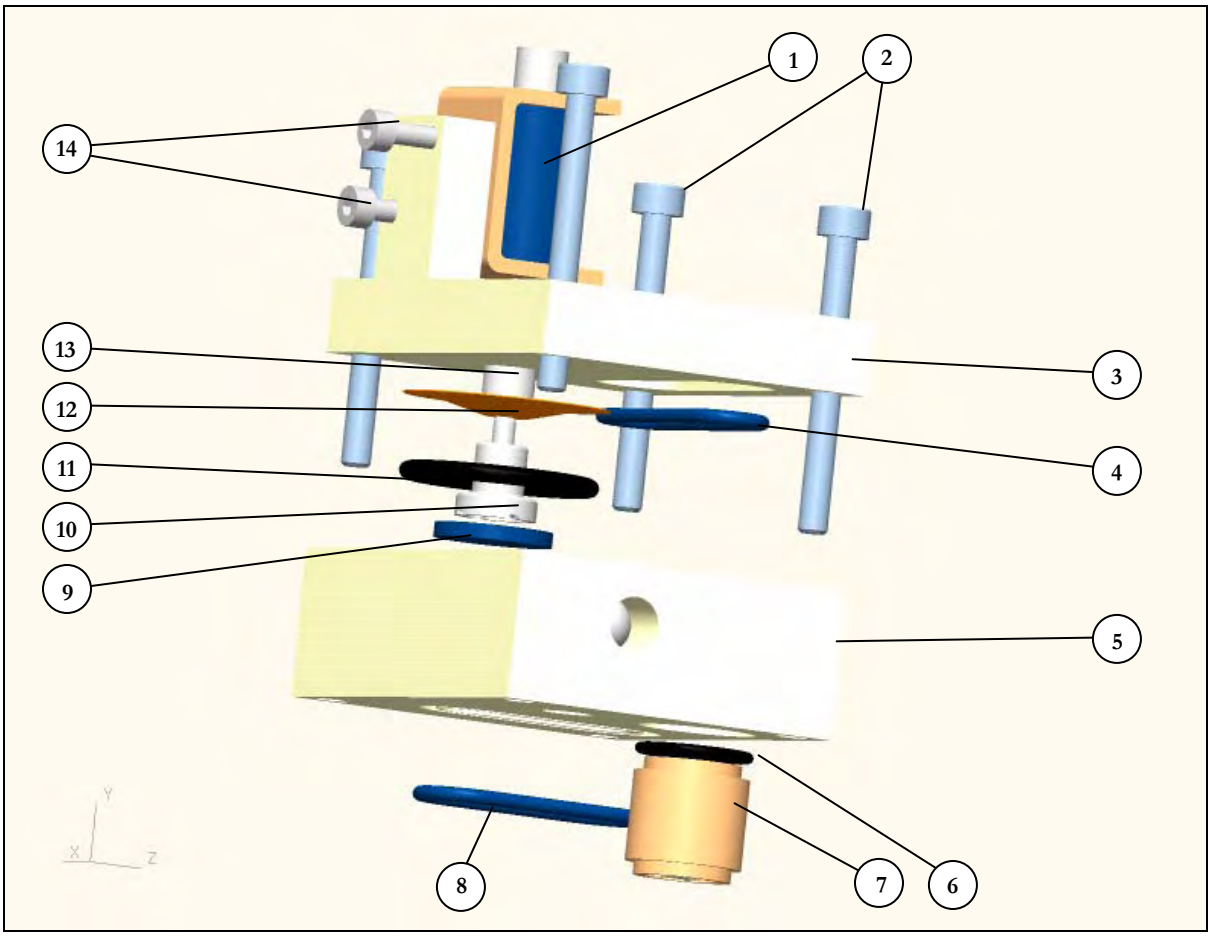
Item No.	Part No.	Description
1	F910309	(PV1) Inspiration Valve
2	F810072	Hex Socket Cap Head screw, M5X40
3	F710301	Sensor Block 1
4	F910081	Internal Flow Sensor, Resistive Element
5	F810034	O-ring, FPM 75.5/VA75, 1.78X4.48
6	F810039	Hex Socket Cap Head screw, M4X60



10.16 Sensor Block 2

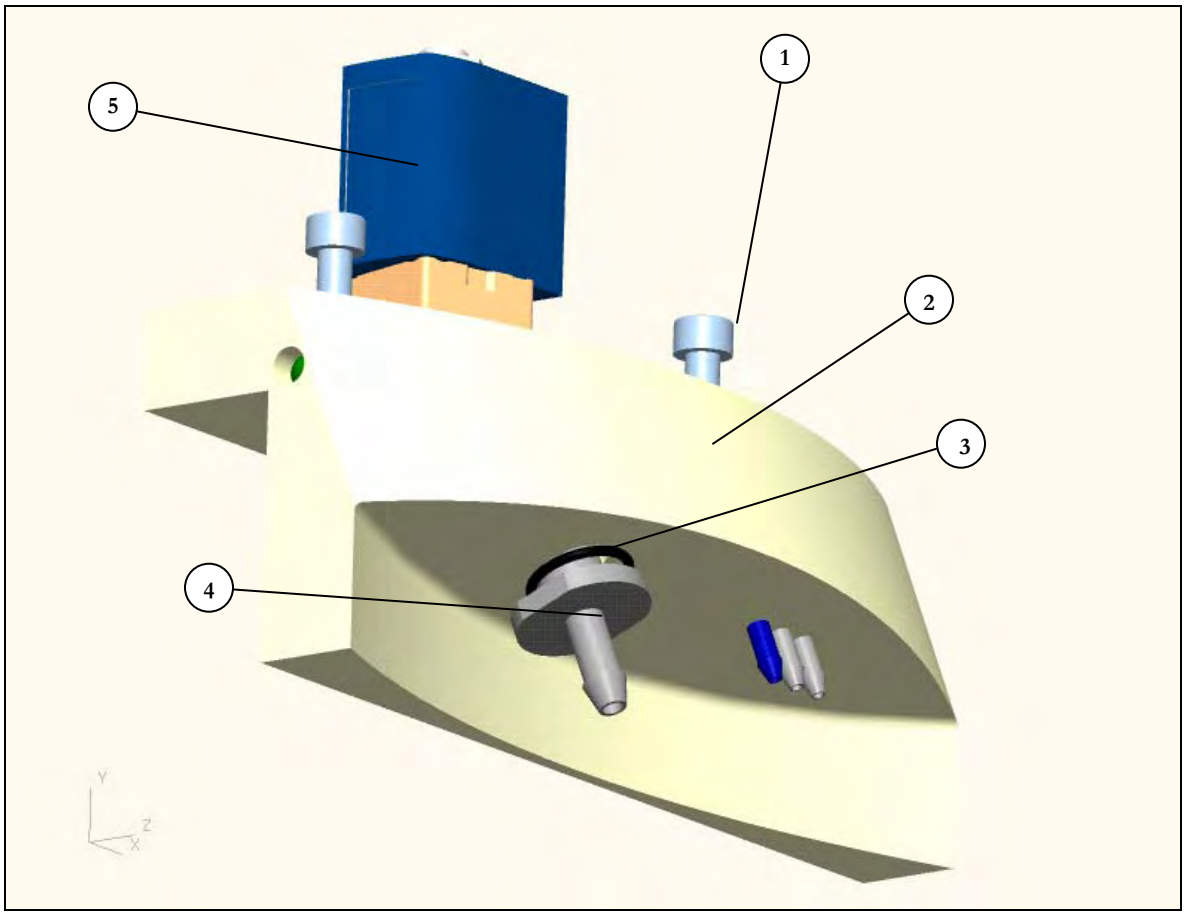
Item No.	Part No.	Description
1	F810032	O-ring, FPM 75.5/VA75, 2.62X9.19
2	F910081	Internal Flow Sensor, Resistive Element
3	F810039	Hex Socket Cap Head screw, M4X60
4	F810034	O-ring, FPM 75.5/VA75, 2X16
5	F810033	O-ring, FPM 75.5/VA75, 1.78X4.48
6	F910240	Sensor Block 2, FRU
7	F810030	O-ring, NBR 70.5/P5, 2.1X3.6
8	F710321	Spacer
9	F920023	Purge Flow Restrictor
10	F810063	O-ring, FPM 75.5/VA75, 1.78X2.9
11	F810029	O-ring, FPM 75.5/VA75, 1.78X6.07
12	F910022	Over Pressure Check valve, 100mbar
13	F810032	O-ring, FPM 75.5/VA75, 2.69X9.19

14	F910025	Compressor Connection Nipple
15	F920100	Blanking Cap G 1/8"
16	F910021	Unloading Valve, Internal Compressor SV3
17	F910200	Silencer, Compressor Unloading
Not Shown	F920101	Compressor Valve Cap, M3
Not Shown	F920102	Hex Socket Cap Head screw, M3X8



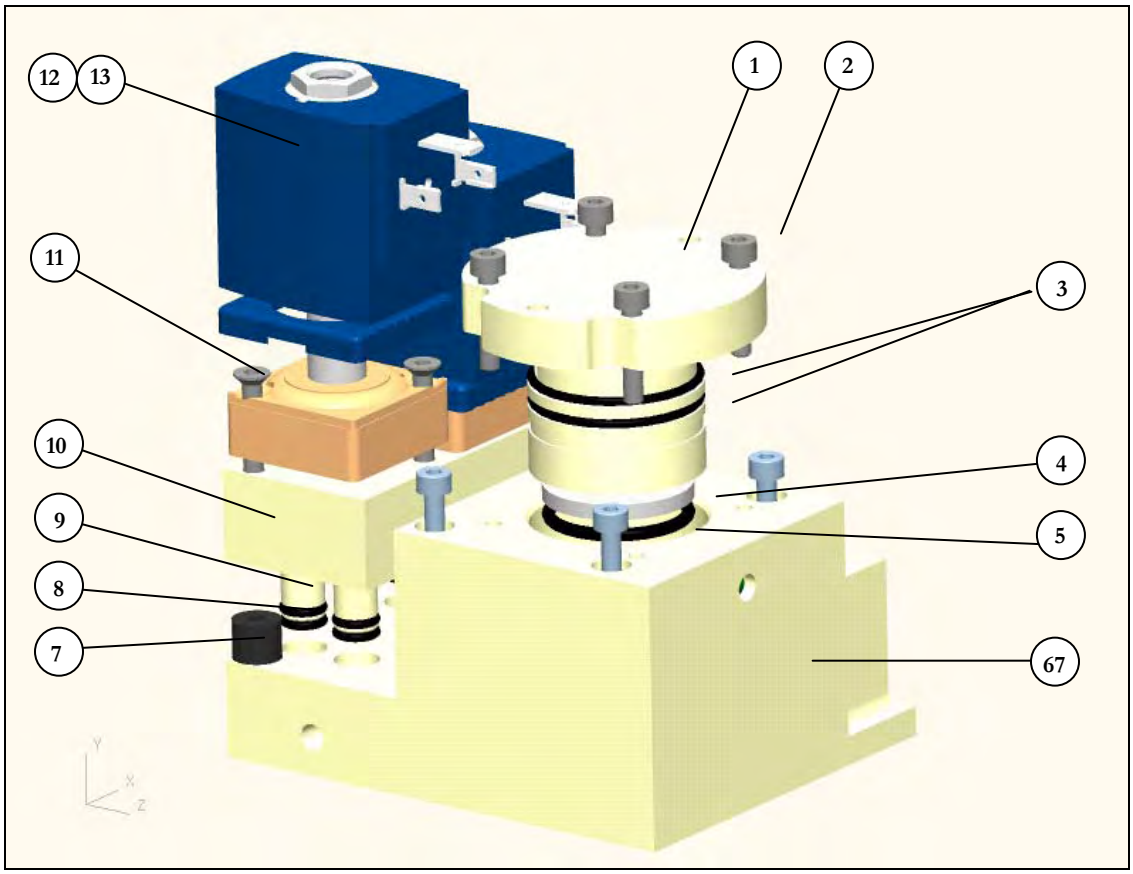
10.17 Safety Valve Block

Item No.	Part No.	Description
1	F910247	Safety Valve Assembly, FRU
2	F810010	Hex Socket Cap Head screw, M4X45
3	F710325	Security Block Cover
4	F810067	O-ring, FPM 75.5/VA75, 2X24
5	F710312	Security Block Base
6	F810037	O-ring, FPM 75.5/VA75, 1.5X13
7	F910030	Over Pressure Check valve O_2 consistent, 120mbar
8	F810067	O-ring, FPM 75.5/VA75,2X24
9	F710326	Sealing disc
10	F710327	Security Valve Plunger
11	F810069	O-ring, FPM 75.5/VA75, 2.5X22
12	F710332	Diaphragm
13	F710331	Aluminum Plunger
14	F810012	Hex Socket Countersunk screw, M6X60



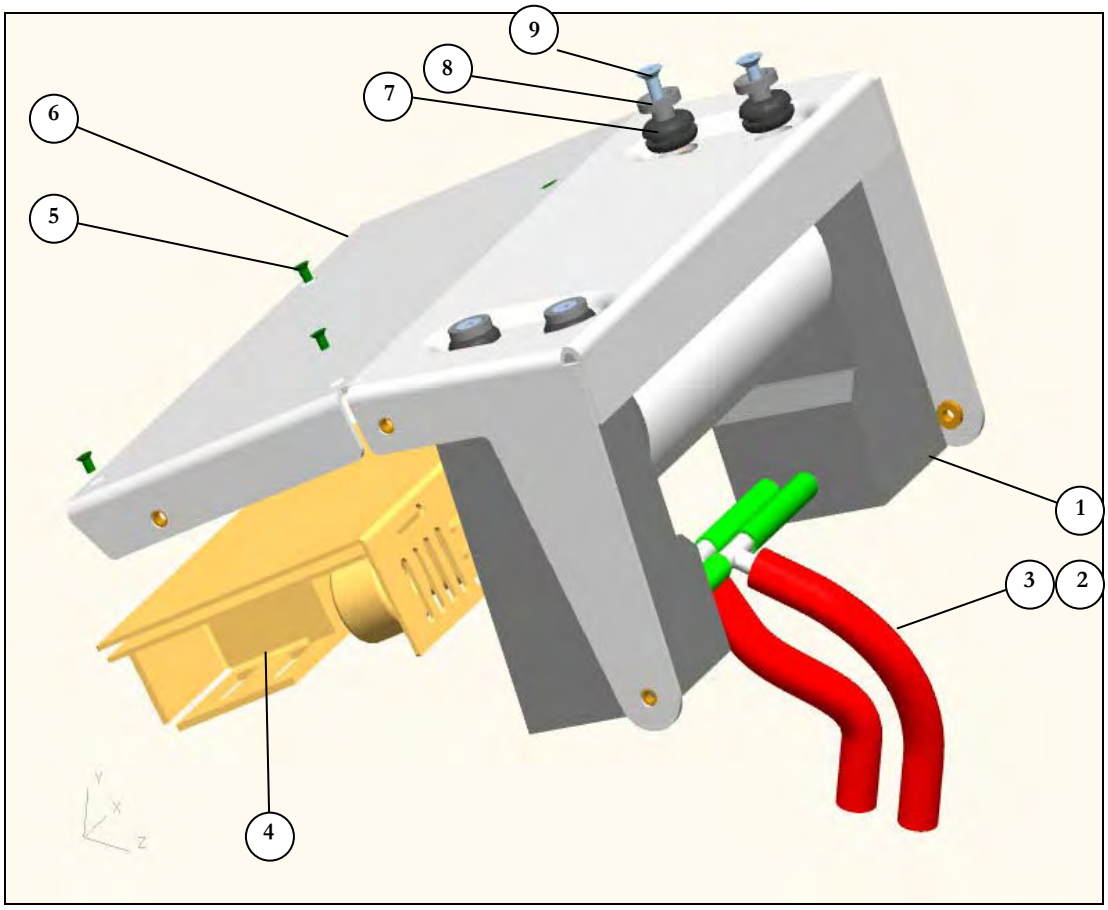
10.18 Front Pneumatic Module

Item No.	Part No.	Description
1	F810005	Hex Socket Countersunk screw, M6X60
2	F910239	Front Interface Block, FRU
3	F810037	O-ring, FPM 75.5/VA75, 1.5X13
4	F710329	Nebulizer Nipple
5	F910026	Nebulizer Solenoid Valve, SV4
Not Shown	F740001	Muffler, Nebulizer Port



10.19 Blender Module

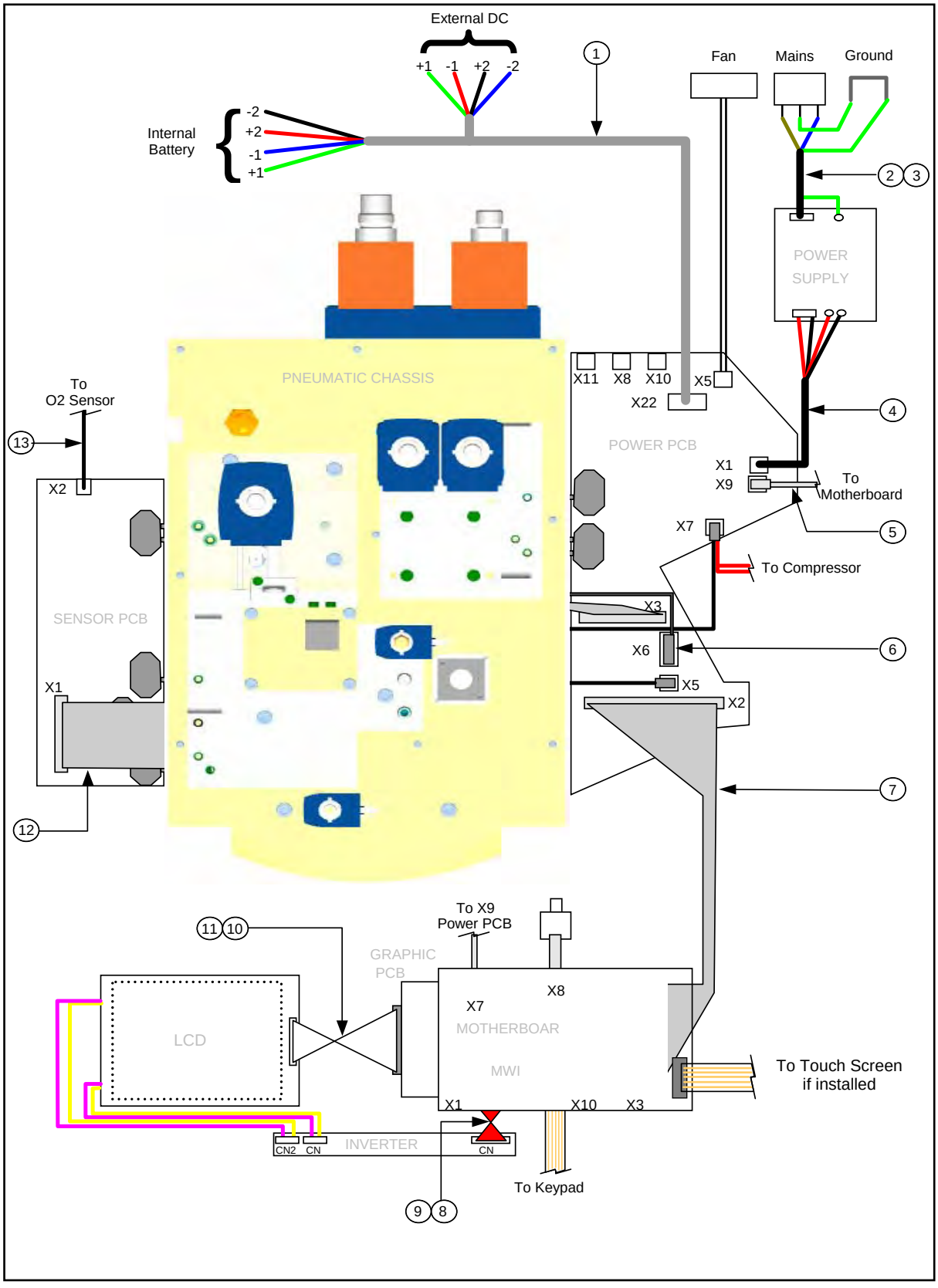
Item No.	Part No.	Description
1	F710401	Blender Holder
2	F810023	Hex Socket Cap Head screw, M4X20
3	F810024	O-ring, FPM 75.5/VA75, 1.78X31.47
4	F710406	Flow Sensor Disc
5	F710405	PS2 O-ring, ID 23.04X3.53mm
6	F710403	Blender Base Block
7	F810026	Rubber Buffer, Type B, 10X8mm, M4
8	F810029	O-ring, FPM 75.5/VA75, 1.78X6.07
9	F710404	Extension Tube
Not Shown	F710409	Asymmetric Extension Tube
Not Shown	F710407	Impact Filter
Not Shown	F710408	O-ring, FKM 75.5/VA75F, ID 23.40X3.53mm
10	F710402	Valve Holder
11	F810021	Hex Socket Countersunk screw, M4X35
12	F910018	Blender Solenoid Valve, SV1/SV2
13	F910018	Blender Solenoid Valve, SV1/SV2



10.20 Compressor Module – INSPIRATION LS / ST

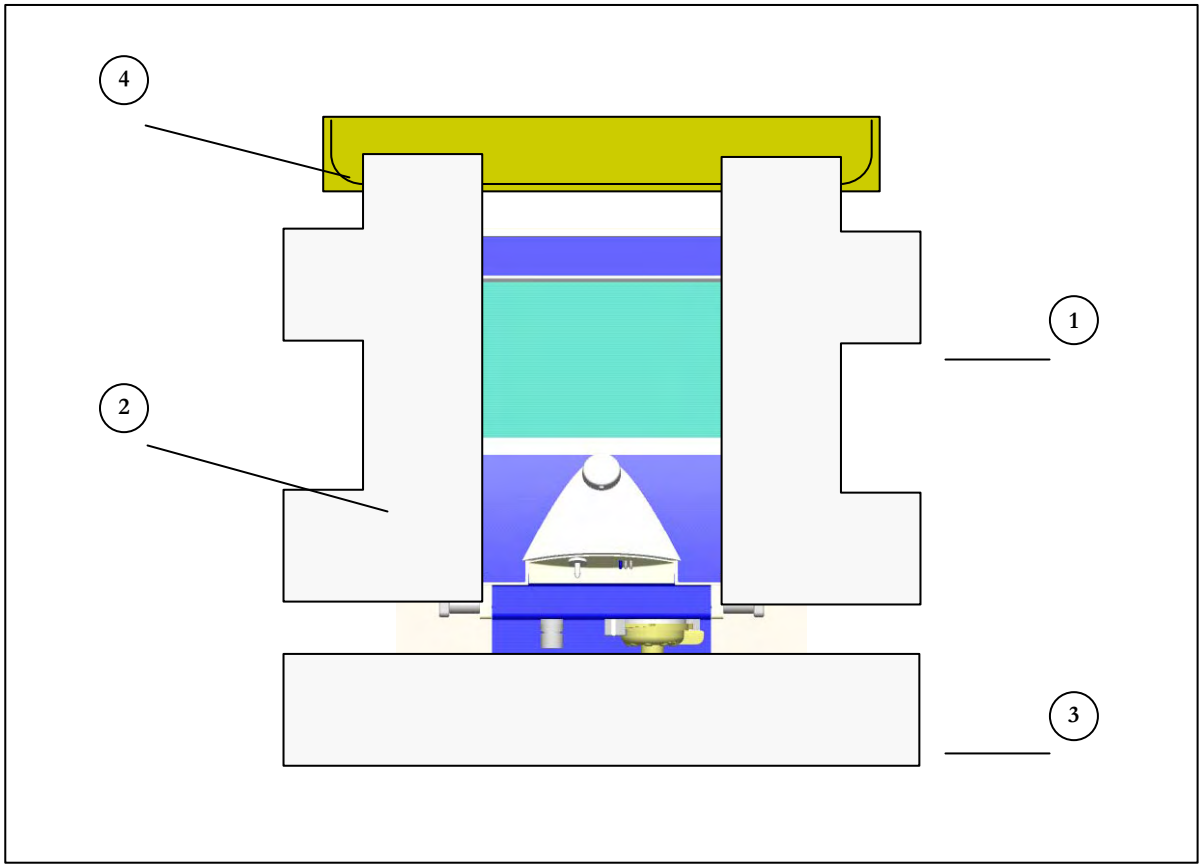
Item No.	Part No.	Description
1	F910249	Compressor, Internal, 8009, FRU
2	F810079	Compressor Supply Tubing
3	F810080	Jubilee Hose Clamp
4	F920010	Power Supply, 24V/150W, FRU
5	F820023	Countersunk screw, NC 4-40, L=3/16"
6	F720601	Compressor Plate
7	F820013	Cable Grommet
8	F720606	Support Bolt
9	F820011	Torx Socket Cap Head screw, M4X16
Not Shown	F910352	Internal Compressor Kit, NC unit
Not Shown	F910033	Warning Sticker, 19X19mm, Yellow/Black
Not Shown	F920071	Earth Cable, 10cm
Not Shown	F920064	O_2 Sensor Cable

INSPIRATION SERIES WIRING DIAGRAM



10.21 Ventilator Wiring

Item No.	Part No.	Description
1	F920063	DC input cable
2	F910071	Power Supply cable
3	F920068	Mains input cable
4	F920066	Power supply cable
5	F920062	Ethernet cable
6	F920067	Valve cable
7	F920060	Controller cable
8	F920070	Inverter cable, 6.4" LCD
9	F930070	Inverter cable, 12.1" LCD
10	F920069	LCD cable, 6.4"
11	F930107	LCD cable, 12.1"
12	F920061	Sensor cable
13	F920064	O_2 sensor cable
Not Shown	F920071	Earth Cable, 10cm (Filter/L Chassis)
Not Shown	F920072	Earth Cable, 18cm (Power PCB)
Not Shown	F920073	Earth Cable, 35cm (O_2 cover)
Not Shown	F920074	Earth Cable, 50cm, front cover
Not Shown	F930003	Earth Cable, 12.1" front



10.22 Inspiration LS Packaging

Item No.	Part No.	Description
--	F-930500	Packaging FRU, LS (includes ref 1,2,3,4)
1		Foam Insert, LS, Right
2		Foam Insert, LS, Left
3		Bottom Insert
4		Accessory Carton
Not Shown	F-930501	Ventilator Carton

10.23 Numeric Parts Listing

P/N	Description
F710102	Inspiration Ventilator Cart, Standard, 100 mm castors
F710203-DE	Nose, German
F710203-ES	Nose, Spanish
F710203-FR	Nose, French
F710203-IN	Nose, English UK & International
F710203-IT	Nose, Italian
F710203-JP	Nose, Japanese
F710203-PL	Nose, Polish
F710203-PT	Nose, Portuguese
F710203-RU	Nose, Russian
F710208	Spacer for Handles
F710209	Side rail, Handle
F710210	Push and turn knob
F710213	Membrane, Event Style
F710213-PKG	Exhalation diaphragm, 10 pack
F710214	E-Valve cover, eVent Style
F710215	DISS O2 Connector, Male
F710216	DISS Air Connector, Male
F710301	Sensor Block 1
F710302	Pneumatic Top Block
F710305	Inspiratory Port
F710308	Oxygen cell tube
F710309	Locking Ring, Outer
F710310	Locking Ring, Inner
F710311	Ring Holder
F710312	Security Block Base
F710313	Gas Inlet Block
F710321	Spacer
F710325	Security Block Cover
F710326	Seal disc with Ref. 780
F710327	Security Valve Plunger
F710329	Nipple for nebulizer

P/N	Description
F710331	Aluminum Plunger
F710332	Diaphragm
F710401	Blender Holder
F710402	Valve Holder
F710403	Blender Base Block
F710404	Extension Tubes
F710405	FS1 O-ring FPM 75.5/VA75F; ID 23.40x3.53mm
F710406	Flow Sensor Disc
F710407	Impact Filter
F710408	O-ring FKM 75.5/VA75F; ID 12.42x1.78mm
F710409	Asymmetric Extension Tube
F710512	Sensor board
F710513	Inspiration Ventilator Cart, Transport
F710519	Cylinder Mounts, Dual US E Cylinder
F710522	Inspiration Ventilator Cart, Deluxe
F710523	Cylinder Mounts, Dual Euro Cylinder
F710562	Inspiration Ventilator Cart, Deluxe, Metallic
F710569	Flex Arm Assembly, Lamtic, BL-3020e
F710570	Tube Hanger, Lamtic, TG-301
F710571	Mounting bracket, Lamtic, MB-06
F710572	Triangle Handle, Lamtic, 3034-T
F710573	Small Handle, Lamtic, 3045
F710574	Mushroom Nut, Lamtic, 3038
F710575	Friction Nut, Lamtic, 3037
F710576	Carriage Bolt, Lamtic, 3048
F710577	Spring, Lamtic, 3049
F720201	Bottom case 7A
F720204	Back plate 7A
F720205	Battery Support
F720206	Battery & O2 Sensor Cover7A
F720207	O2 Sensor Cover
F720211	Display glass 6.4"
F720217	Guide rail

P/N	Description
F720241	Batteries holder
F720510	Motherboard
F720511	Power board
F720515-DE	Lexan screen 6.4", German
F720515-ES	Lexan screen 6.4", Spanish
F720515-FR	Lexan screen, French
F720515-IN	Lexan screen 6.4", English
F720515-IT	Lexan screen 6.4", Italian
F720515-JP	Lexan screen 6.4", Japanese
F720515-PL	Lexan screen 6.4", Polish
F720515-PT	Lexan screen 6.4", Portuguese
F720515-RU	Lexan screen 6.4", Russian
F720601	Compressor Module Plate
F720606	Compressor Support Bolt
F720701	Bracket, Graphic Module
F720703	Print Support Sheet
F730202	Top housing coated 12.1"
F730203-DE	Nose, German
F730203-ES	Nose, Spanish
F730203-FR	Nose, French
F730203-UK	Nose, English UK & International
F730203-IT	Nose Italian
F730203-JP	Nose, Japanese
F730203-PL	Nose, Polish
F730203-PT	Nose, Portuguese
F730203-RU	Nose, Russian
F730210	Push and turn knob
F730221	Hinge, PU
F730513	DC Converter PCB, LS only
F730515-DE	Lexan screen 12.1", German
F730515-ES	Lexan screen 12.1", Spanish
F730515-FR	Lexan screen 12.1", French
F730515-IN	Lexan screen 12.1", English

P/N	Description
F730515-IT	Lexan screen 12.1", Italian
F730515-JP	Lexan screen 12.1", Japanese
F730515-PL	Lexan screen 12.1", Polish
F730515-PT	Lexan screen 12.1", Portuguese
F730515-RU	Lexan screen 12.1", Russian
F730701	Connection plate 12.1" for Motherboard
F730710	Nose cone grey, LS
F730711	Bottom Housing, Grey
F730712	Top Housing, Metallic Grey
F730713	Back Plate, Grey
F730714	Battery Cover, Grey
F730715	Encoder, 6.5" cable
F730716	Encoder Knob LS, Grey
F730717	PU Housing, Metallic Grey
F730721-DE	12.1" Lexan screen Grey, German
F730721-ES	12.1" Lexan screen Grey, Spanish
F730721-FR	12.1" Lexan screen Grey, French
F730721-IN	12.1" Lexan screen, Grey, English
F730721-IT	12.1" Lexan screen Grey, Italian
F730721-JP	12.1" Lexan screen Grey, Japanese
F730721-PL	12.1" Lexan screen Grey, Polish
F730721-PT	12.1" Lexan screen Grey, Portuguese
F730721-RU	12.1" Lexan screen Grey, Russian
F730727	Encoder Knob Ring
F730730	PU Housing, TS
F730731	Touch Screen
F730732	Encoder earth cable
F730734	Graphic Cable
F730735	Display Adapter PCB
F730738-DE	Kit, Upgrade, Touch Screen, Grey to Grey LS, German
F730738-ES	Kit, Upgrade, Touch Screen, Grey to Grey LS, Spanish
F730738-FR	Kit, Upgrade, Touch Screen, Grey to Grey LS, French
F730738-IN	Kit, Upgrade, Touch Screen, Grey to Grey LS, English

P/N	Description
F730738-IT	Kit, Upgrade, Touch Screen, Grey to Grey LS, Italian
F730738-JP	Kit, Upgrade, Touch Screen, Grey to Grey LS, Japanese
F730738-PL	Kit, Upgrade, Touch Screen, Grey to Grey LS, Polish
F730738-PT	Kit, Upgrade, Touch Screen, Grey to Grey LS, Portuguese
F730738-RU	Kit, Upgrade, Touch Screen, Grey to Grey LS, Russian
F730741	Inspiration 12.1" LCD, LB121S03
F730742	Inverter PCB, New
F730743	Inverter Cable, New
F730744	Inspiration Ventilator Cart, Transport, Grey
F740001	Muffler, Nebulizer Port (LS Infant Only)
F740007-xx	Infant nose cone
F750001-XX	Infant Nose Cone, LS – Initial Release
F750002-IN	12.1" Infant Lexan Screen Grey, English
F750002-DE	12.1" Infant Lexan Screen Grey, German
F750002-ES	12.1" Infant Lexan Screen Grey, Spanish
F750002-FR	12.1" Infant Lexan Screen Grey, French
F750002-IT	12.1" Infant Lexan Screen Grey, Italian
F750002-JP	12.1" Infant Lexan Screen Grey, Japanese
F750002-PL	12.1" Infant Lexan Screen Grey, Polish
F750002-PT	12.1" Infant Lexan Screen Grey, Portuguese
F750002-RU	12.1" Infant Lexan Screen Grey, Russian
F750515-JP	Lexan screen 12.1" Infant, Japanese
F750515-UK	Lexan screen 12.1" Infant, English
F810001	External DC connector
F810004	Mounting Screw, Rail
F810005	Mounting Screws
F810007	O-ring, high pressure connectors
F810008	Screw, water trap
F810010	Screw, safety valve block cover
F810011	Threaded pin (Gewindestift) M4x8
F810011-PKG	PKG 10, Threaded pin (Gewindestift) M4x8
F810012	Hex Socket Cap Head Screw M3x10
F810012-PKG	PKG 10, Hex Socket Cap Head Screw M4x12

P/N	Description
F810015	Screw, cooling fan
F810016	Hex Socket Cap Head Screw M4x12
F810016-PKG	PKG 10, Hex Socket Cap Head Screw M4x12
F810017	Hex Socket Countersunk Screw M3 x 12
F810017-PKG	PKG 10, Hex Socket Countersunk Screw M3 x 12
F810018	Screw Nut M3
F810019	Serrated Lockwasher M3
F810021	Hex Socket Countersunk Screw M4x35
F810021-PKG	PKG 10, Hex Socket Countersunk Screw M4x35
F810023	Hex Socket Cap Head Screw M4x20
F810023-PKG	PKG 10, Hex Socket Cap Head Screw M4x20
F810024	O-Ring FPM 75.5/VA75 1.78x31.47
F810024-PKG	PKG 10, O-Ring FPM 75.5/VA75 1.78x31.47
F810026	Rubber Buffer Type B, 10x8mm, M4
F810026-PKG	PKG 4, Rubber Buffer Type B, 10x8mm, M4
F810029	O-Ring FPM 75.5/VA75 1.78x6.07
F810029-PKG	PKG 10, O-Ring FPM 75.5/VA75 1.78x6.07
F810030	O-Ring NBR 70.5/P5, 2.4x3.6
F810030-PKG	PKG 10, O-Ring NBR 70.5/P5, 2.4x3.6
F810031	O-Ring FPM 75.5/VA75, 2.62x4.42
F810031-PKG	PKG 10, O-Ring FPM 75.5/VA75, 2.62x4.42
F810032	O-Ring FPM 75.5/VA75, 2.62x9.19
F810032-PKG	PKG 10, O-Ring FPM 75.5/VA75, 2.62x9.19
F810033	O-Ring FPM 75.5/VA75, 1.78x4.48
F810033-PKG	PKG 10, O-Ring FPM 75.5/VA75, 1.78x4.48
F810034	O-Ring FPM 75.5/VA75, 2x16
F810034-PKG	PKG 10, O-Ring FPM 75.5/VA75, 2x16
F810037	O-Ring FPM 75.5/VA75, 1.5x13
F810037-PKG	PKG 10, O-Ring FPM 75.5/VA75, 1.5x13
F810039	Hex Socket Cap Head Screw M4x60
F810039-PKG	PKG 10, Hex Socket Cap Head Screw M4x60
F810041	Hex Socket Cap Head Screw M3x25
F810041-PKG	PKG 10, Hex Socket Cap Head Screw M3x25

P/N	Description
F810042	O-Ring FPM 75.5/VA75, 1.78x17.17
F810042-PKG	PKG 10, O-Ring FPM 75.5/VA75, 1.78x17.17
F810044	Inlet Filter, Compressor
F810059	Hex Socket cap Head Screw M4x25
F810059-PKG	PKG 10, Hex Socket cap Head Screw M4x25
F810061	Inlet Check Valve, Air / O2, 7.5 mbar
F810063	O-Ring FPM 75.5/VA75, 1.78x2.9
F810063-PKG	PKG 10, O-Ring FPM 75.5/VA75, 1.78x2.9
F810067	O-Ring FPM 75.5/VA75 2x24
F810067-PKG	PKG 10, O-Ring FPM 75.5/VA75 2x24
F810069	O-Ring FPM 75.5/VA75 2,5x22
F810069-PKG	PKG 10, O-Ring FPM 75.5/VA75 2,5x22
F810072	Hex Socket Cap Head Screw M5x40
F810072-PKG	PKG 10, Hex Socket Cap Head Screw M5x40
F810075	Hex Socket Cap Head Screw M3x5(for Processor Board and Mini Web Interface)
F810075-PKG	PKG 10, Hex Socket Cap Head Screw M3x5(for Processor Board and Mini Web Interface)
F810079	Compressor Supply Tubing, Silicon UNISIL ID=6mm, OD=12mm, L=TBA
F810079-PKG	PKG 1 metre, Compressor Supply Tubing, Silicon UNISIL ID=6mm, OD=12mm, L=TBA
F810080	Jubilee Hose Clamp 11.5-12.5mm / 10-13.3mm
F810080-PKG	PKG 10, Jubilee Hose Clamp 11.5-12.5mm / 10-13.3mm
F810082	Hex Socket Countersunk Screw M3x12
F810082-PKG	PKG 10, Hex Socket Countersunk Screw M3x12
F810085	O-Ring, FPM 75.5/VA75, 2.4 x 3.3mm
F810085-PKG	PKG 10, O-Ring, FPM 75.5/VA75, 2.4 x 3.3mm
F810087	Distance bolt M3 L=7mm, SW=5mm (for Processor Board and Mini Web Interface)
F810087-PKG	PKG 10, Distance bolt M3 L=7mm, SW=5mm (for Processor Board and Mini Web Interface)
F810088	Hex Socket Cap Head Screw M3x6
F810088-PKG	PKG 10, Hex Socket Cap Head Screw M3x6
F810132	Self tapping screw for nose Plastite No.6 1/4 Pan Head

P/N	Description
F810132-PKG	PKG 10, Self tapping screw for nose Plastite No.6 1/4 Pan Head
F810135	Fuse 3.15AT / 250V
F810135-PKG	PKG 5, Fuse 3.15AT / 250V
F810203	Threaded Insert, M4
F810204	O-Ring FPM 75.5/VA75, 2x12
F810204-PKG	PKG 10, O-Ring FPM 75.5/VA75, 2x12
F810216	Hex Socket Countersunk Screw M4 x 8
F810216-PKG	PKG 10, Hex Socket Countersunk Screw M4 x 8
F810217	Power cord retainer P-Clip (US -JP)
F810245	M4x12 Hex Countersunk Stainless Steel screw
F810245-PKG	PKG 10, M4x12 Hex Countersunk Stainless Steel screw
F820004	Long belt
F820005	Short Belt
F820006	Damping Mat
F820007	Screw, Graphic Plate
F820009	Hex Socket Cap Head Screw M4x50
F820009-PKG	PKG 10, Hex Socket Cap Head Screw M4x50
F820010	Threaded Insert, M6
F820011	Torx socket cap head screw M4x16
F820011-PKG	PKG 10, Torx socket cap head screw M4x16
F820013	Cable grommet
F820013-PKG	PKG 10, Cable grommet
F820015	Distance Pin (Stand Off) M2 L=30mm, SW=4mm (for LCD)
F820015-PKG	PKG 10, Distance Pin (Stand Off) M2 L=30mm, SW=4mm (for LCD)
F820016	Distance Pin (Stand Off) M3, L=10mm, SW=5mm (for Graphic board and Inverter)
F820016-PKG	PKG 10, Distance Pin (Stand Off) M3, L=10mm, SW=5mm (for Graphic board and Inverter)
F820018	Hex Socket Cap Head Screw M2x8 (for LCD)
F820018-PKG	PKG 10, Hex Socket Cap Head Screw M2x8 (for LCD)
F820019	Distance bolt, M3x18mm, Polyamide (Power PCB)
F820019-PKG	PKG 10, Distance bolt, M3x18mm, Polyamide (Power PCB)
F820020	Collar for screw, M3, (Power PCB)
F820020-PKG	PKG 10, Collar for screw, M3, (Power PCB)

P/N	Description
F820021	Hex Socket Cap Head Screw M3x10, Stainless Steel
F820021-PKG	PKG 10, Hex Socket Cap Head Screw M3x10, Stainless Steel
F820022	Hex Socket Countersunk Screw, (Power PCB) M3x10
F820022-PKG	PKG 10, Hex Socket Countersunk Screw, (Power PCB) M3x10
F820023	Countersunk screw for Power supply UNC 4-40, L=3/16"
F820023-PKG	PKG 10, Countersunk screw for Power supply UNC 4-40, L=3/16"
F820024	EMC Ferrite Bead
F820025	Clip, EMC Ferrite Bead
F830001	Philips Screw, K40 x 10
F830001-PKG	PKG 10, Philips Screw, K40 x 10
F830005	Hex Socket Cap Head Screw, M2 x 5, (for Inverter)
F830005-PKG	PKG 10, Hex Socket Cap Head Screw, M2 x 5, (for Inverter)
F830006	Hex Socket Fillister Head Screw, M3 x 8 (for DC/DC)
F830006-PKG	PKG 10, Hex Socket Fillister Head Screw, M3 x 8 (for DC/DC)
F830007	Bolt Spacer Round, 3.1 x 3, (DC/DC)
F830007-PKG	PKG 10, Bolt Spacer Round, 3.1 x 3, (DC/DC)
F910005	Encoder switch
F910006	Cooling Fan, 60mm x 60mm
F910007	Cooling Fan filter (with guard, cover & filter)
F910008	Power entry module 4A, Type 5220
F910009	P-Clip 6mm; UL-94V-2
F910015	Processor Board
F910016	Compressed Air Filter / Water Trap, with Micro Filter Bit 1/8"
F910018	Blender Solenoid Valve SV1/SV2
F910021	Unloading Valve - Internal Compressor SV3
F910022	Over Pressure Check Valve 100mbar, For Proximal Sensor
F910025	Compressor Connection Nipples
F910026	Nebulizer Solenoid, SV4
F910027	Restrictor, O2 Measurement
F910028	Galvanic Oxygen Sensor
F910030	Over pressure Check Valve, O2 consistent, 120mbar
F910031	Security Valve
F910033	Warning Sticker 19x19mm Yellow/Black

P/N	Description
F910037	DISS Air Hose Assembly
F910038	DISS O2 Hose Assembly
F910081	Internal Flow Sensor - Resistive Element
F910085	SW Download Cable
F910089	Mini Web Interface FRU
F910089UT	Mini Web Interface ,Unit Tested
F910200	Silencer, Compressor Unloading
F910201	Tank Over Pressure Valve
F910203PKG	Disposable Adult Sensor, 10 pack
F910204PKG	Disposable Infant Sensor, 10 pack
F910205	Filter Element (for Inlet Filter Ref.no. 319)
F910210	Label, "Do Not Obstruct"
F910211	Label "to Patient", "from Patient" - Japanese
F910214	Fan Filter Element (5 pack)
F910216	Bowl, Water trap
F910217	High Pressure Hose 2m – Air – DISS to BOC
F910218	High Pressure Hose 2m – O2 – DISS to BOC
F910219	High Pressure Hose ITA - Air
F910220	High Pressure Hose ITA - O2
F910239	Front Interface Block, FRU
F910240	Sensor Block 2, FRU
F910241	Top Housing 6.4", FRU
F910242	Pneumatic Bottom Block, FRU
F910243	O2 Sensor Block, LS/ST, FRU
F910244-DE	Front Housing PU Complete FRU – German
F910244-ES	Front Housing PU FRU Complete – Spanish
F910244-FR	Front Housing PU Complete FRU – French
F910244-IN	Front Housing PU Complete FRU - English UK & International
F910244-IT	Front Housing PU Complete FRU – Italian
F910244-JP	Front Housing PU Complete FRU - Japanese (Fukuda)
F910244-PL	Front Housing PU Complete FRU – Polish
F910244-PT	Front Housing PU Complete FRU - Portuguese
F910245	O-Ring Tank Main, FRU

P/N	Description
F910246	O-Ring Evalve enclosure, FRU
F910247	Safety Valve Assembly, FRU
F910249	Compressor Assembly, 8009, FRU
F910250	LCD 12.1", FRU
F910251	Internal Battery Pack, FRU
F910252	Fan Cooling, FRU
F910260	Tubing, EZ Flow Sensor, SPU, (10 Pack)
F910309	PV1 Inspiration Valve, 00168731
F910310	PV2 Exhalation Valve 4401102B03 Rev 06
F910340	Valve Enhancement Kit FRU
F910341	PV1 Inspiration Valve, 82908920 FRU
F910342	PV2 Exhalation Valve 4401102B03 FRU
F910344	Flow Sensor Internal, FS1, LG &LS FRU
F910345	Impact Filter FRU
F910352	Internal Compressor kit for NC Unit
F920001	6.4" VGA TFT Display
F920010	Power supply 24V/150W, FRU
F920023	Purge Flow Restrictors
F920023-PKG	PKG 2, Matched, Purge Flow Restrictors
F920060	Controller cable
F920061	Sensor cable (Ribbon cable)
F920062	Ethernet cable
F920063	DC input cable
F920064	O2 sensor cable
F920066	Power supply cable
F920067	Valve cables
F920068	Mains input cable
F920069	Cable for 6.4" LCD
F920070	Inverter cable for 6.4" LCD unit
F920071	Earth Cable, 10cm, (Filter / L Chassis)
F920072	Earth Cable, 18cm, (Power PCB)
F920073	Earth Cable, 35cm, (O2 Cover)
F920074	Earth Cover, 50cm, (Front Chassis)

P/N	Description
F920100	Blanking Cap G1/8"
F920101	Cap for compressor valve M3
F920102	Hex socket head cap screw M3x8
F920104	Inverter for 6.4" LCD Optrex
F920105	Backlight Assembly, ST
F920115	Valve Cable FRU
F920116	Compressor Unloading valve FRU
F920117	Nebulizer Valve FRU
F920118	Security Valve FRU
F920119	Power Supply 24V, 6.4" & 12.1"
F920123	Compressor Cable FRU
F920124	6.4" Graphic Board, DCUL7, V3.5 software
F930001	12.1" SVGA TFT Display
F930002	Graphic Board DCUL4-IMT1 with plugs and SW for 12.1" LG LCD
F930003	Earth Cable, 12.1 Front
F930069	Cable for 12.1" LCD
F930070	Inverter cable for 12.1" LCD unit
F930104	Inverter for 12.1" LCD Optrex
F930105	Backlight Assy, ST
F930106	LCD, 12.1"
F930107	LCD Cable, 12.1"
F930111	12.1" Graphic Board, DCUL7, V3.5 software
F930137-XX	Front Housing Grey PU Complete, FRU
F930138	Nose Cone c/w Knob, English. FRU
F930139	Nose Cone c/w Knob, Spanish. FRU
F930140	Nose Cone c/w Knob, Russian. FRU
F930141	Nose Cone c/w Knob, Japanese. FRU
F930142	Nose Cone c/w Knob, Polish. FRU
F930143	Nose Cone c/w Knob, German. FRU
F930144	Nose Cone c/w Knob, French. FRU
F930145	Nose Cone c/w Knob, Italian. FRU
F930146	Nose Cone c/w Knob, Portuguese. FRU
F930147	Nose Cone c/w Knob, Chinese. FRU

P/N	Description
F930148	Nose Cone, English. FRU
F930149	Nose Cone, Spanish. FRU
F930150	Nose Cone, Russian. FRU
F930151	Nose Cone, Japanese. FRU
F930152	Nose Cone, Polish. FRU
F930153	Nose Cone, German. FRU
F930154	Nose Cone, French. FRU
F930155	Nose Cone, Italian. FRU
F930156	Nose Cone, Portuguese. FRU
F930157	Nose Cone, Chinese. FRU
F930160-XX	Touch Screen Front Housing, Grey PU XX: (Language version of the applied lexan screen)
F930168	Front Housing PU Complete, TS(Includes ref 1)
F930501	Ventilator Carton 12.1
F930503	Foam Insert - Left, 12.1
F930504	Foam Insert - Right, 12.1
F930505	Foam Insert - Bottom, 12.1
F930506	Device Bag, Polythene, 12.1
F930507	Accessory Carton, 12.1
F950004-XX	Infant Front Housing Grey PU Complete, FRU
F950005	Infant Nose Cone c/w Knob, English. FRU
F950006	Infant Nose Cone c/w Knob, Spanish. FRU
F950007	Infant Nose Cone c/w Knob, Russian. FRU
F950008	Infant Nose Cone c/w Knob, Japanese. FRU
F950009	Infant Nose Cone c/w Knob, Polish. FRU
F950010	Infant Nose Cone c/w Knob, German. FRU
F950011	Infant Nose Cone c/w Knob, French. FRU
F950012	Infant Nose Cone c/w Knob, Italian. FRU
F950013	Infant Nose Cone c/w Knob, Portuguese. FRU
F950014	Infant Nose Cone c/w Knob, Chinese. FRU
F950015	Infant Nose Cone, English. FRU
F950016	Infant Nose Cone, Spanish. FRU
F950017	Infant Nose Cone, Russian. FRU

P/N	Description
F950018	Infant Nose Cone, Japanese. FRU
F950019	Infant Nose Cone, Polish. FRU
F950020	Infant Nose Cone, German. FRU
F950021	Infant Nose Cone, French. FRU
F950022	Infant Nose Cone, Italian. FRU
F950023	Infant Nose Cone, Portuguese. FRU
F950024	Infant Nose Cone, Chinese. FRU

Section

11

COMMUNICATION INTERFACE

11.1 Introduction

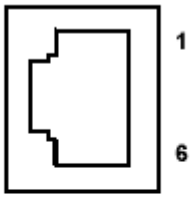
For convenience the following section provides a detailed description of how to configure the Inspiration Ventilators nurse call and serial communication ports.

For the serial communication interface, a full listing is provided for all relevant commands and SNDA responses.

11.2 Nurse Call Port Configuration

The nurse call port allows the Inspiration series ventilator to be connected to a remote alarm system. Nurse call pin assignments (floating contacts) are shown in Figure 11-1 below.

Pin	Function
1	Not in use
2	NC (Normal Closed)
3	NO (Normal Open)
4	Not in use
5	Common
6	Not in use



Ventilator connector: Nurse Call

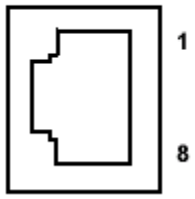
Figure 11-1

11.3 Serial (RS-232) Port Configuration

Pin assignments for the Serial (RS-232) Port of the Inspiration series ventilator are as shown on Figure 11-2 below.

RS232 interface pin assignments:

Pin	Function
1	DCD (Data Carrier Detect)
2	RTS (Ready To Send)
3	CTS (Clear To Send)
4	DTR (Data Terminal Ready)
5	GND (Ground)
6	DSR (Data Set Ready)
7	RXD (Receive Data)
8	TXD (Transmit Data)



Ventilator connector: RS232

Figure 11-2

11.4 Serial (RS-232) port setup

Serial port parameters for the Inspiration series ventilator are pre-configured and may not be adjusted by the user. The settings in use are as follows:

Baud Rate: 9600

Data Bits: 8

Stop Bits: 1

Parity: OFF

Flow Control: OFF

11.5 Serial (RS-232) Inspiration protocol

This protocol is specifically designed for the Inspiration ventilator family and allows complete monitoring of all settings and measurements. For specific information about this protocol please refer to RS232 eVent Inspiration Protocol V1.1.

11.6 Serial (RS-232) port commands

The communications port responds to these commands facilitating communication to and from the ventilator using the serial ports:

RSET: clears the data from the ventilators receive buffer

SNDA: tells the ventilator to send ventilator settings and monitored data to the host system

11.7 RSET (clear ventilator buffer)

Enter the RSET command exactly like this:

RSET <CR>

- Where <CR> is a carriage return. The ventilator only responds if it receives a carriage return. When the ventilator receives the RSET command, it clears it's receive buffer. The ventilator does not send a response to the host system.

11.8 SNDA (send ventilator settings and data)

Enter the SNDA command exactly like this:

SNDA<CR>

- Where <CR> is a carriage return. The ventilator responds only if it receives a carriage return. When the ventilator receives the SNDA command, it responds with a code MISCA, followed by the ventilator settings and monitored data information.

  The MISCA response follows the format shown in Figure 11-3 below.

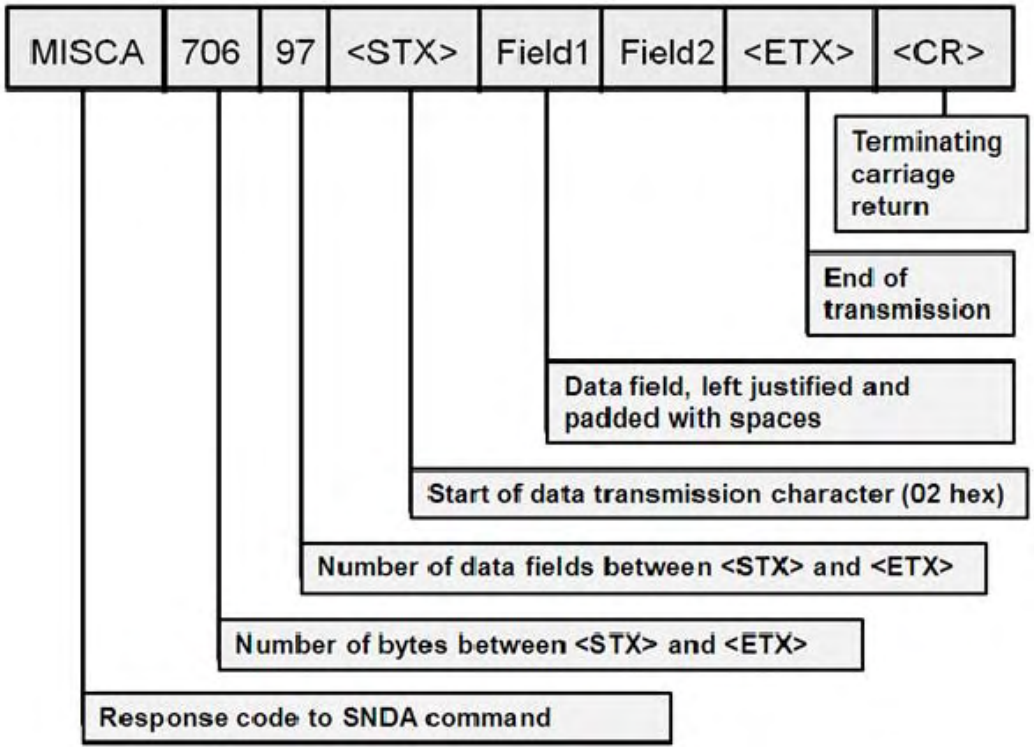


Figure 11-3

Note:

The MISCA command response is designed to be compatible with the MISCA command response from Puritan-Bennett Ventilators, including the 7200, 700 series and 800 series. In the fields where the command response differs from that of the Puritan-Bennett ventilators, the difference is noted in the field description.

Field Number	Field Content
1	MISCA (5 characters)
2	706 (3 characters; the number of bytes between <STX> and <ETX>)
3	97 (2 characters; the number of fields between (<STX> and <ETX>)
4	<STX> (start of transmission)
5	Ventilator time (HH:MM_) (6 characters)
6	Not used (13 characters)
7	Not used (6 characters)
8	Not used (12 characters)
9	Mode setting (6 characters)
10	Respiratory rate setting (6 characters)
11	Tidal volume setting (6 characters)
12	Peak flow setting (6 characters)
13	O2% setting (6 characters)
14	Not used (6 characters)
15	PEEP/ CPAP setting (6 characters)
16	Plateau time (6 characters)
17	Not used (6 characters)
18	Not used (6 characters)
19	Not used (6 characters)
20	Not used (6 characters)
21	Apnea interval (6 characters)
22	Apnea tidal volume setting (6 characters)
23	Apnea respiratory rate setting (6 characters)
24	Apnea peak flow setting (6 characters)
25	Apnea O2% setting (6 characters)
26	Pressure support setting (6 characters)
27	Inspiratory flow pattern (6 characters)
28	Not used (6 characters)
29	Nebulizer setting (On or Off) (6 characters)
30	100% O2 setting (On or Off) (6 characters)
31	Not used (6 characters)
32	Not used (6 characters)
33	Not used (6 characters)
34	Total respiratory rate (6 characters)
35	Exhaled tidal volume (6 characters)
36	Exhaled minute volume (6 characters)
37	Spontaneous minute volume (6 characters)
38	Peak airway pressure (6 characters)

Field Number	Field Content
39	Mean airway pressure (6 characters)
40	End inspiratory pressure (6 characters)
41	Not used (6 characters)
42	High pressure limit (6 characters)
43	Low inspiratory pressure (6 characters)
44	Not used (6 characters)
45	Low tidal exhaled tidal volume (6 characters)
46	Low exhaled minute volume (6 characters)
47	High respiratory rate (6 characters)
48	High pressure alarm status (6 characters)
49	Low inspiratory pressure alarm status (6 characters)
50	Not used (6 characters)
51	Low tidal volume alarm status (6 characters)
52	Low minute volume alarm status (6 characters)
53	High respiratory rate alarm status (6 characters)
54	Low O2 supply alarm status (6 characters)
55	Not used (6 characters)
56	Low internal battery alarm (6 characters)
57	Apnea alarm status (6 characters)
58	Not used (6 characters)
59	Not used (6 characters)
60	Not used (6 characters)
61	Not used (6 characters)
62	Not used (6 characters)
63	Static compliance (6 characters)
64	Static resistance (6 characters)
65	Dynamic compliance (6 characters)
66	Dynamic resistance (6 characters)
67	Not used (6 characters)
68	Not used (6 characters)
69	Not used (6 characters)
70	Not used (6 characters)
71	Flow sensitivity setting (6 characters)
72	Not used (6 characters)
73	Not used (6 characters)
74	Not used (6 characters)
75	Not used (6 characters)
76	Not used (6 characters)
77	Not used (6 characters)

Field Number	Field Content
78	Not used (6 characters)
79	Not used (6 characters)
80	Not used (6 characters)
81	Not used (6 characters)
82	Not used (6 characters)
83	Not used (6 characters)
84	Not used (6 characters)
85	PC inspiratory pressure setting (6 characters)
86	Inspiratory time setting (6 characters)
87	Not used (6 characters)
88	PC apnea pressure setting (6 characters)
89	PC apnea rate setting (6 characters)
90	PC apnea inspiratory time setting (6 characters)
91	PC apnea O2% setting (6 characters)
92	Not used (6 characters)
93	Alarm silence state (6 characters)
94	Apnea alarm status (6 characters)
95	Disconnect alarm status (6 characters)
96	Not used (6 characters)
97	Not used (6 characters)
98	Not used (6 characters)
99	Not used (6 characters)
100	Not used (6 characters)
101	Monitored I:E ratio (6 characters)
102	<ETX>
103	<CR>

Section

12

SOFTWARE INSTALLATION INSTRUCTIONS

These instructions describe in detail how to successfully install new main system and mini-web interface software to the Inspiration® Ventilator system.

WARNING

In order to ensure proper operation and avoid the possibility of physical injury, only qualified personnel should attempt to service, perform installations, or make other authorized modifications to the ventilator.

The user of this product shall retain sole responsibility for any ventilator malfunction due to operation or maintenance performed by persons not trained by the manufacturer.

12.1 Suggested Tools and Equipment

Description	Manufacturer
Computer (Minimum Win 98, Pentium based system)	Local Supplier
Software Download Cable	eVent Medical, F910085
Inspiration Download Software	eVent Medical, Download.exe
Software File	eVent Medical, eventXYZ.tim

12.2 Installation Process:

12.2.1 Pre Installation Tests:

Verify the operational status of the ventilator prior to proceeding with the software installation:

- Switch the ventilator On in normal operation mode.
- Verify the ventilator completes self-test without reporting technical errors.
- Should any errors be reported refer to the Diagnostic Error Codes and Alarm Messages section of this manual for further details and correct the alarm condition prior to proceeding.
- Switch the device on in configuration mode. On completion of power on self-test record the SW Ventilator Version from the Standby screen.
- Switch device off.

Verify the software download utility is installed to desktop on your computer:

- Installation of Inspiration system software requires the use of a proprietary download utility called download.exe.
- The download.exe should be installed to desktop prior to commencing the software download process.
- Install the utility program to desktop or to a convenient file location.

Verify the required version of software is available on your computer:

- During software download you are required to install the latest version of system software on your ventilator.
- The required software file should be stored to a convenient file location prior to commencing the download.
- To verify that you have the latest version of software available you may contact eVent Medical at service@event-medical.com.
- Save the software file eventX.Y.Z.tim to a convenient file location.

CAUTION

For safety and convenience, only the current release version of system software should be retained on your PC. As each new software version is released and downloaded please ensure that old versions are deleted or archived.

12.3 System Software Download Procedure (Ventilator / MWI Software)

- Ensure that you have at least one serial communications port available for communication with the ventilator.
- Attach the software download cable (F910085) to an available RS232 port on your PC as shown in Figure 12-1.
- If installing main ventilator system software, connect the opposite end of the software download cable to the RS232 port on the ventilator's rear panel.
- If installing mini-web interface software, connect the opposite end of the software download cable to the Ethernet port on the ventilator's rear panel.

CAUTION

As defined above ensure that the software download cable is attached to the correct rear panel port for the software to be installed. Incorrect connection will result in corruption of NVRAM calibration data.

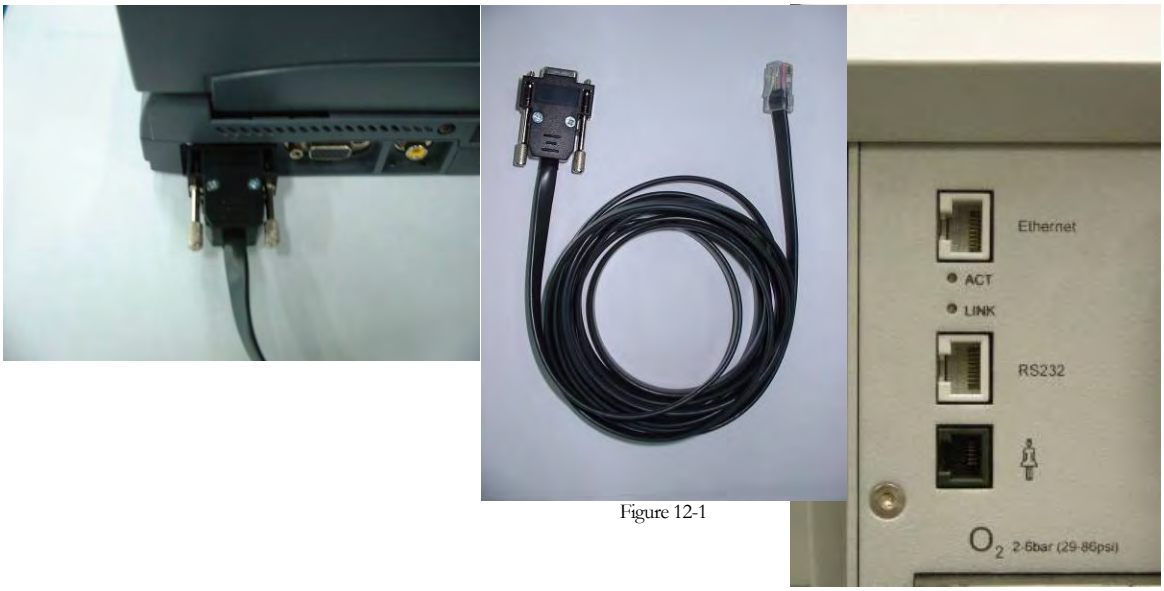


Figure 12-1

- Double-click the download.exe icon located on your desktop (previously installed) in order to start the download process and follow the on screen instructions.
- Choose Select File on the firmware selection screen and a window listing the software files available locally on your PC appears (Figure 12-2).
- Select and Open the appropriate file for the software to requiring installation. Software files available are broken down as follows:
    - Main System Software eVentVX.X.X.tim
    - Mini Web System Software eVentMWIVX.X.X.tim
    - Mini Web Applet Software eVentWebAppletV.X.X.X.tim
- Ensure the correct file and extension is now listed on the main screen then select Next to proceed to next step.

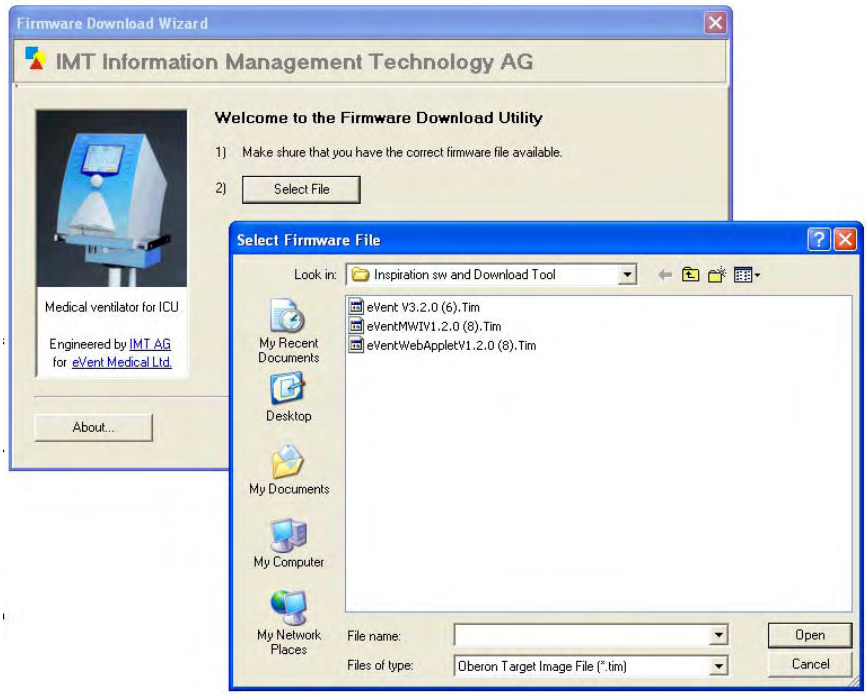


Figure 12-2

Firmware Download Wizard
IMT Information Management Technology AG
Choose COM Port
3) Make shure that you have connected the device with a COM port on your PC
4) Choose one of the following available COM ports:
Auto
Auto will search on all available COM ports
Backup compressor for medical air supply
Engineered by IMT AG for imtmedical.ag
About...
< Back
Next >

Figure 12-3

- The next screen, shown in Figure 12-3, prompts you to select which of your computer's communication ports you will use for the download process.
- This may be set for com 1 or com 2, alternatively if using any other port (such as a PCMCIA serial connection). Select Auto and the download utility will sense which port is in use.
- Select Next to proceed to the next step.
- The next step, shown in Figure 12-4 attempts to establish communication with the ventilator through the appropriate Com port.

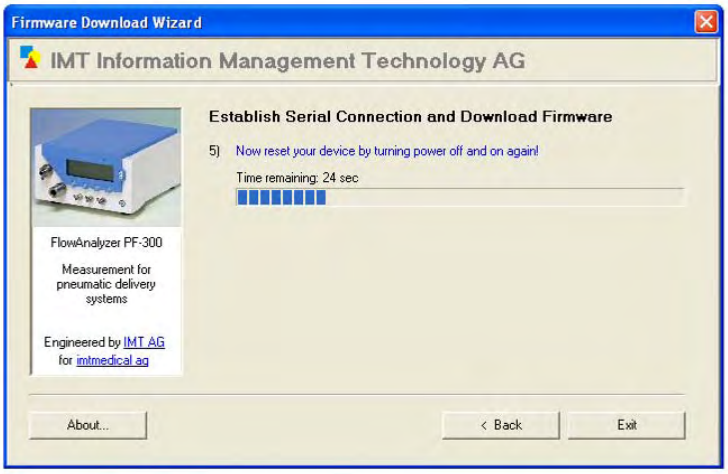

Firmware Download Wizard
IMT Information Management Technology AG
Establish Serial Connection and Download Firmware
5) Now reset your device by turning power off and on again!
Time remaining: 24 sec
FlowAnalyzer PF-300
Measurement for pneumatic delivery systems
Engineered by IMT AG for imtmedical ag
About...
< Back
Exit

Figure 12-4

- You are prompted at this point to reset the ventilator. If the device is Off, simply switch it On within the 30 second time window. If it is on already, simply switch it Off then On again within the 30 second time window.

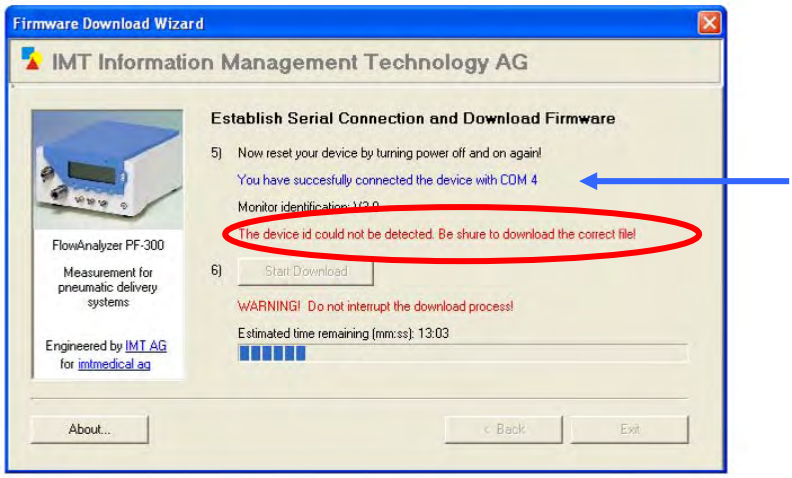

Firmware Download Wizard
IMT Information Management Technology AG
Establish Serial Connection and Download Firmware
5) Now reset your device by turning power off and on again!
You have succesfully connected the device with COM 4
The device id could not be detected. Be shure to download the correct file!
6) Start Download
WARNING! Do not interrupt the download process!
Estimated time remaining (mm:ss): 13:03
FlowAnalyzer PF-300
Measurement for pneumatic delivery systems
Engineered by IMT AG for imtmedical ag
About...
< Back
Exit

Figure 12-5

- Observe the screen for confirmation of a successful connection by the statement You have successfully connected to the device with COM X (Indicated by the arrow in Figure 12-5.) Ignore the statement: The device id could not be detected. Be sure to download the correct file. (Indicated by the circle in Figure 12-5.)
- In the event that connection is not confirmed, repeat the entire system software download procedure and troubleshoot connections as is necessary.
- With a successful connection the screen will confirm that the device is ready for download.
- Select Start Download and the process will commence.

CAUTION

The download procedure should not be interrupted once it is in progress.
The download window will confirm when the process has been successfully completed.
Upon completion, switch the device Off and remove the download cable.

12.4 Power Software Installation Procedure

- Remove and set aside the ventilators top housing (LG only.) Reference the Service and Repair Procedures section of this manual.
- Open the front housing of the ventilator (LS only.) Reference the Service and Repair Procedures section of this manual.
- Ensure that you have at least one serial communications port available for communication with the ventilator.
- Attach the software download cable to the available serial port on your PC as shown in Figure 12-1.
- Attach the other end of the software download cable to the vacant connector on the Power board immediately adjacent to the Soft Ware Flash EPROM shown in Figure 12-7.

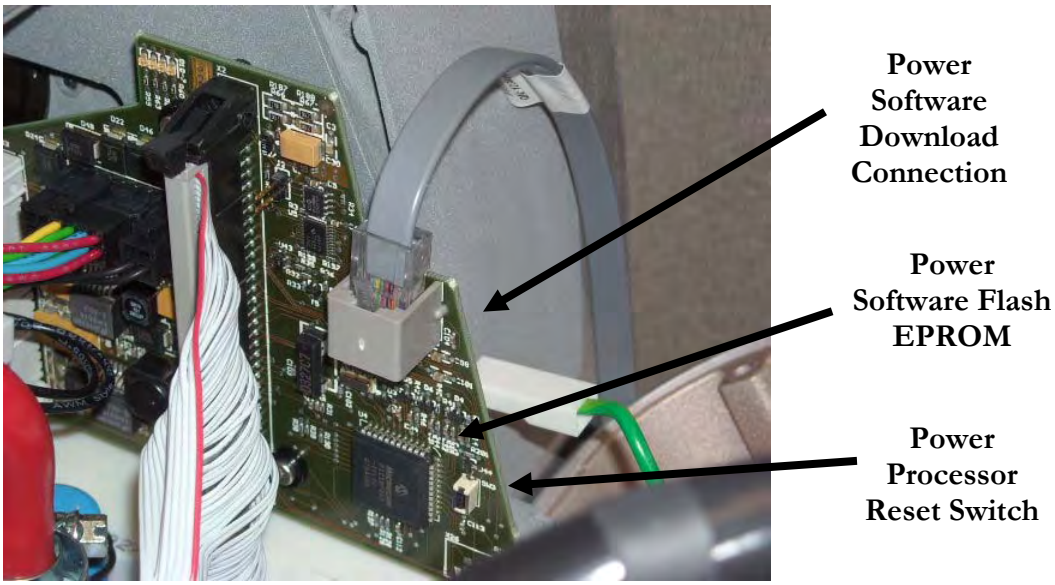


Figure 12-6

- The procedure is performed largely as described above in the System Software Download Procedure with the following alterations.
- At the firmware selection stage, change file type to **.hex** and select file in the form eVent PowerboardVX.X.X.hex as shown in Figure 12-7 below.

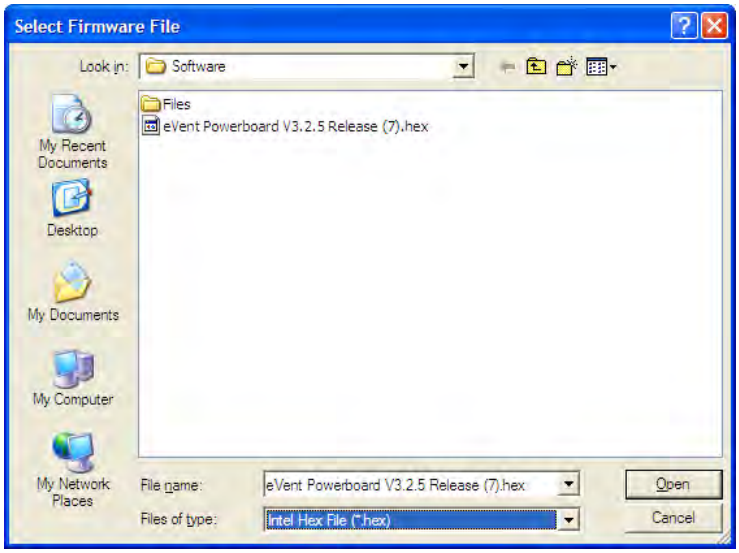


Figure 12-7

- You are prompted by the download application screen to power cycle (Off/On) the ventilator at the beginning and end of the download process.
- Whenever prompted to do this, press the power processor reset switch positioned immediately adjacent to the Power board Flash EPROM. See Figure 12-6.

12.5 Post Software Installation Checks

- Switch on the ventilator and allow it to run through system test.
- Should self-test report an OK status, the device may be switched off and returned to operational use.
- Should self-test report any status other than OK, refer to the Technical Error Listing and Troubleshooting: table found in the DIAGNOSTIC ERROR CODES and ALARM MESSAGES (Section 8) of this manual.

NOTE

Some releases of system software may require that additional calibration, configuration and other steps be performed before the device may be returned to operational use. Refer to the software release notes or applicable Technical Information Bulletins for verification of these additional requirements.

12.6 Troubleshooting

In the event of experiencing any problems or technical errors, refer to the Technical Error Listing and Troubleshooting: table found in the DIAGNOSTIC ERROR CODES and ALARM MESSAGES section (8) of this manual.

12.7 Technical Assistance

Should you experience any problems during or following the upgrade process, please contact your local eVent Medical representative.

Alternatively you may contact eVent Medical directly at our group email address service@event-medical.com .

Section

13

FORMS

For your convenience and use you will find on the following pages a Service Record/Warranty Claim form. You should complete this document when performing any procedures on the Inspiration Ventilator system.

You will also find a Performance Verification Record to use with the Performance Verification section of this manual.

Completed field service record / customer complaint forms should be forwarded as appropriate to one of the following locations:

Worldwide:

eVent Medical, Inc.

971 Calle Amanecer

Suite 101

San Clemente CA, 92673

United States of America.

Phone: +1 949 492 8368

Fax: +1 949 492 8382

service@event-medical.com

eVent Medical

INSPIRATION SERIES VENTILATOR – PERFORMANCE VERIFICATION RECORD

Customer:	Software Vent:
	Software Power:
	Software Graphic:
Model: ☐ Inspiration LS ☐ Inspiration ST ☐ Original	Hardware Power:
Serial Number:	Hardware Controller:
Next PM Due:	Hardware Sensor:
	Hardware Graphic:

Ventilator Hours:	(FabTest 11)	Compressor Hours:	(FabTest 11

Electrical Safety Tests	Target	Actual	Adjusted
Ground Resistance	<0.2 OHM	Ω	Ω
Forward Current Leakage	≤300μA (all units)	μA	μA
Reverse Current Leakage	≤300μA (all units)	μA	μA

Power On Self Test / Configuration	Limit	Result	Pass Y / N	
Self Test Status	OK		☐ Yes	☐ No

Fabrication Test (FabTest 5)	Limit	Result	Pass Y / N	
Re-Zero All Pressure Transducers	OK		☐ Yes	☐ No

Calibrations and System Leak Test:	Limit	Result	Pass Y / N	
System Leak Test Results	OK		☐ Yes	☐ No
System Compliance	N/A		☐ Yes	☐ No
Proximal Sensor Calibration	OK		☐ Yes	☐ No
Oxygen Sensor Calibration	OK		☐ Yes	☐ No

Performance Test 1 Gas Volume Accuracy:	Limit	Result	Pass Y / N	
Tidal Volume (Vti) (Pneumatic Analyzer)	20ml +/- 3ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte) (Ventilator)	20ml +/- 3ml		☐ Yes	☐ No
Respiratory Rate (Pneumatic Analyzer)	40b/min +/- 0.5b/min		☐ Yes	☐ No
Tidal Volume(Vti) (Pneumatic Analyzer)	100ml +/- 15ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte) (Ventilator)	100ml +/- 15ml		☐ Yes	☐ No
Respiratory Rate (Pneumatic Analyzer)	30b/m in+/- 0.4b/min		☐ Yes	☐ No
Tidal Volume(Vti) (Pneumatic Analyzer)	300ml +/- 25ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte) (Ventilator)	300ml +/- 25ml		☐ Yes	☐ No
Respiratory Rate (Pneumatic Analyzer)	20b/min +/- 0.3b/min		☐ Yes	☐ No

Tidal Volume (Vti) (Pneumatic Analyzer)	600ml +/- 40ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte) (Ventilator)	600ml +/- 40ml		☐ Yes	☐ No
Respiratory Rate (Pneumatic Analyzer)	15b/min +/- 0.25b/min		☐ Yes	☐ No

Tidal Volume (Vti) (Pneumatic Analyzer)	1000ml +/- 60ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte) (Ventilator)	1000ml +/- 60ml		☐ Yes	☐ No
Respiratory Rate (Pneumatic Analyzer)	8b/min +/- 0.18b/min		☐ Yes	☐ No

Smart Sigh Test	5 consecutive sigh breaths delivered after 20 normal breaths		☐ Yes	☐ No
Tidal Volume (Vti) (Pneumatic Analyzer)	750ml +/- 47.5ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte) (Ventilator)	750ml +/- 47.5ml		☐ Yes	☐ No

Performance Test 2: Pressure Accuracy:	**Limit**	**Result**	**Pass Y / N**	
Pcontrol (10cmH20)	10cmH20 +/- 2.25cmH20		☐ Yes	☐ No
Pcontrol (50cmH20)	50cmH20 +/- 3.25 cmH20		☐ Yes	☐ No
Smart Sigh Pcontrol (15cmH2O)	15cmH2O +/- 2.375 cmH2O		☐ Yes	☐ No
PEEP (5cmH20)	5cmH20 +/- 2.2 cmH20		☐ Yes	☐ No
PEEP (30cmH20)	30cmH20 +/- 3.2 cmH20		☐ Yes	☐ No
PEEP (50cmH20)	50cmH20 +/- 4.0 cmH20		☐ Yes	☐ No

Performance Test 3 Oxygen Delivery:	**Limit**	**Result**	**Pass Y / N**	
Oxygen 21% Analyzer	21% +/- 3%		☐ Yes	☐ No
Oxygen 21% Vent	21% +/- 3%		☐ Yes	☐ No
Oxygen 60% Analyzer	60% +/- 3		☐ Yes	☐ No
Oxygen 60% Vent	60% +/- 3		☐ Yes	☐ No
Oxygen 100% Analyzer	100% +/- 3		☐ Yes	☐ No
Oxygen 100% Vent	100% +/- 3		☐ Yes	☐ No

Performance Test 4 Alarm Operation:	**Limit**	**Result**	**Pass Y / N**	
Disconnect Alarm	On		☐ Yes	☐ No
Alarm Mute – On	On		☐ Yes	☐ No
Alarm Mute – OFF	Off		☐ Yes	☐ No
Alarm Mute – Time	120 sec +/- 12 sec		☐ Yes	☐ No
Disconnect Alarm	Reset		☐ Yes	☐ No

HIP Alarm On	On		☐ Yes	☐ No
Alarm Reset	Off		☐ Yes	☐ No

Apnea Alarm On	On		☐ Yes	☐ No
Apnea Ventilation	On		☐ Yes	☐ No
Apnea Ventilation	Off		☐ Yes	☐ No

Performance Test 5 Gas Sources: Test 1	**Limit**	**Result**	**Pass Y / N**	
Loss O2	Loss O2 Alarm		☐ Yes	☐ No
O2 Reset	Alarm Cancels		☐ Yes	☐ No
Loss Air	Compressor Starts		☐ Yes	☐ No
Air Reset	Compressor Stops		☐ Yes	☐ No
Loss Air / Compressor	Loss Air Alarm		☐ Yes	☐ No
Loss All Supply	Loss Air / O2		☐ Yes	☐ No
Loss All Supply	Int. Pressure Low		☐ Yes	☐ No
Loss All Supply Reset	Alarm Cancels		☐ Yes	☐ No

Service Representative:_____ Date: _____

Service Report / Warranty Claim Form			eVent Medical
Form Number: QUALITY-0008	Revision Number: 09	Page of	

Tracking Number:

Service / Warranty Information

Date Created:		*Service Type:	
Requested By:		Customer Reference:	
Request Received Via:		PO Number:	
If Other, explain:		RGA Number:	

Customer / Distributor Details

*Name:		Address:	
Company:		City:	
Title or Department:		State/Province:	
*Phone Number:		Postal Code:	
Contact Email Address:		Country:	
Hospital Name:		Hospital Address:	

Equipment Details

Model:		*Serial Number:	
*Ventilator Hours:		*Compressor Hours:	
*SW Version (pre svc):		*SW Version (post svc):	
*Power SW (pre svc):		*Power SW (post svc):	
MiniWeb SW (pre svc):		MiniWeb SW (post svc):	
Date of Installation:		*Date of Event:	

Details of Work Performed

Service Description:

Please give a full description of the service performed.
Include the following information if applicable: PM due date, error codes, alarm details, reported problems, and failure conditions

Resolution:

Describe actions taken to resolve the problem

Tracking Number:

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Details of Patient Involvement (Death OR Serious Injury; DORSI)

*Was there a patient involvement? Yes No

*Did Death or Serious Injury occur? Yes No

*Was medical intervention required? Yes No

Other relevant information:

Condition of patient at the time of event and current condition:

Name and Contact details of medical professional confirming DORSI:

Supporting Documentation:	

Service / Warranty Resolution Details

Resolution Details:	

Service Report / Warranty Claim Form			eVent Medical
Form Number: QUALITY-0008	Revision Number: 09	Page of	

Tracking Number:

Parts Used During Service / Repair

Part Number	Description of Part	SN Removed	SN Installed	Warranty Claim (Y/N)

	Return this Form and Parts to:
Supporting Documentation:	eVent Medical, Inc. T: +1.949.492.8368 971 Calle Amanecer Suite 101 F: +1.949.492.8382 San Clemente, CA 92673 USA
Service Completed By:	Date:
For Internal Use Only:	

Service Reviewed By:	Name	Date	Signoff Status

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